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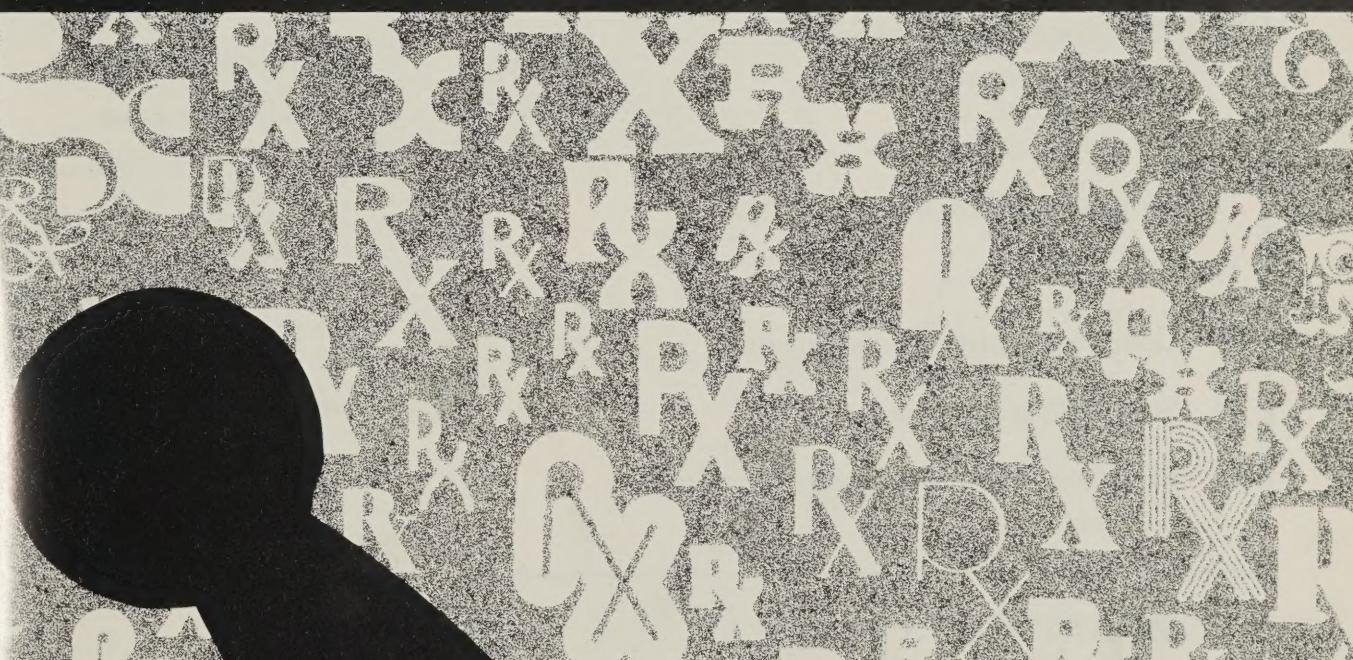
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THE
MARYLAND
PHARMACIST

Official Journal of
The Maryland
Pharmacists
Association

January, 1988
VOL. 64
NO. 1

MARYLAND PHARMACIST



Bronchodilator Drugs

—J. Richard Wuest, Thomas Gossel

The Pharmacist and Hospice

—Diane White, Lynda Oderda, Ilene Zuckerman

Proposed MPhA Bylaws

1988 Tax Dates

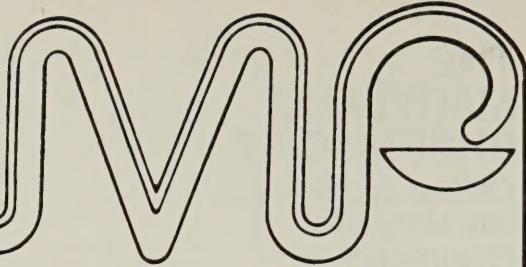
Commentary by Jim Dickinson

Steroid Prescriptions

Free Continuing Education Programs

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
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VOL. 64

NO. 1

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PRESIDENT'S MESSAGE

In recent years pharmacies have been adding systems at an accelerated rate that are capable of monitoring and tracking the patient's use of prescription medication. At the same time schools of pharmacy throughout the nation have shifted their curriculum from the product preparation and dispensing aspect of pharmacy practice, to the more scientific principles of drug action, drug interactions, drug-food interactions, etc.

The consuming public is aware of our expertise in drug matters, knows that pharmacists are the most accessible of all health professionals, and places more trust in our profession than any other health care profession.

All the pieces are in place now. We as professionals must use these tools and our acquired knowledge to communicate more effectively with our patients. Surprising a recent study indicated that pharmacists only interact face-to-face with their patients 56% of the time; yet this form of communication has been shown to be the most effective method of improving patient compliance.

Improved communications could also reduce the number of prescriptions (estimated to be between 30 to 50%) which fail to produce desired results because they are used improperly. In addition, it is estimated that \$500,000 worth of annual hospital admissions are related to drug reactions.

Finally it is this easy accessibility and direct pharmacist-patient contact that stimulates business, builds consumer loyalty and places us head and shoulders above mail order pharmacies and physician dispensers.

Editors Note: We regret to inform our readers that, after many years of support, District Photo has discontinued it's monthly advertisement in the *Maryland Pharmacist* effective with this issue.

Lee Ahlstrom, P.D.

PRESIDENT

CONTINUING EDUCATION FOR PHARMACISTS

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. IV, NO. 12

Advising Consumers on OTC Bronchodilator Drugs

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Goals

The goals of this lesson are to:

1. discuss the actions and reactions of OTC product ingredients used in the treatment of asthma; and
2. present advice for consumers to assure maximum efficacy from these drugs.

Objectives

At the conclusion of this lesson, participants will be able to:

1. list the pharmacologic and toxicologic actions associated with bronchodilator drugs;
2. explain the rationale for combining different bronchodilator drugs in treating asthma;
3. select from a list of drugs, those reported to interact adversely with bronchodilators;
4. match the route of administration with selected bronchodilators;
5. cite specific warnings that are appropriate for bronchodilators; and
6. list advice for consumers that will assure maximum therapeutic activity from OTC bronchodilator drugs.

Bronchodilator drugs are indicated specifically for the treatment of asthma. This disease is characterized by widespread narrowing of respiratory passages due to spasms of bronchiolar smooth muscle. Symptoms include chest tightness, shortness of breath, and wheezing.

The body's immune response, associated with the asthma syndrome, causes bronchoconstriction. This leads to partial obstruction of airflow within the pulmonary system. Spasms can cause narrowing of airways which may eventually subside spontaneously, or be controlled by drug therapy. Bronchial infections, acute or chronic bronchitis, pulmonary emphysema (widespread destruction of lung tissue), and pulmonary congestion involving left ventricle failure can also cause the airway to narrow.

This article discusses bronchodilator drugs used as ingredients in OTC asthma remedies. It elaborates on their mechanisms of action, and discusses their adverse reactions and drug interactions. It also lists specific information for consumers using these products.

OTC Bronchodilator Drugs

Bronchodilators are mainstays in the treatment of asthma. There are two different pharmacologic groups that possess this activity: the sympathomimetic amines and the xanthine derivatives. While differing in mechanism of action, they both bring about the same therapeutic effect.

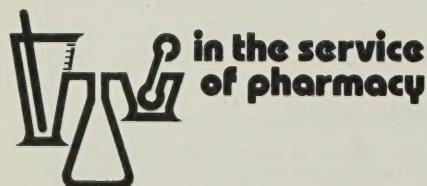
Bronchodilators relax airway muscle spasm and thereby, relieve disease manifestations. They are taken orally to ameliorate symptoms, or may be inhaled in aerosolized form to abort attacks. Disease of mild-to-moderate intensity normally responds quickly to such medication.

FDA stresses the importance of having bronchodilators available over-the-counter. Persons diagnosed with mild asthma can then obtain quick relief without possible delays waiting to obtain a prescription.

When FDA's Advisory Panel on OTC Bronchodilators reviewed these agents, it indicated that the drugs are safe for OTC use, but undesirable effects can occur. These include increased rate and force of the heartbeat, rise in blood pressure, nervousness and sleeplessness, and nausea or vomiting.

Sympathomimetic Amines. Sympathomimetic amines (adrenergics, beta agonists) that stimulate beta₂-adrenergic receptors located in the walls of bronchial smooth muscle activate the enzyme adenylyl cyclase (Figure 1). This converts intracellular adenosine triphosphate (ATP) to cyclic adenosine monophosphate (cAMP). Increased cAMP levels enhance binding of calcium to cell membranes and endoplasmic reticulum. Total ionic calcium within the cell is reduced, and the smooth muscle relaxes.

Beta₁-adrenergic agonists also increase the activity of cilia lining the respiratory passages. These normally



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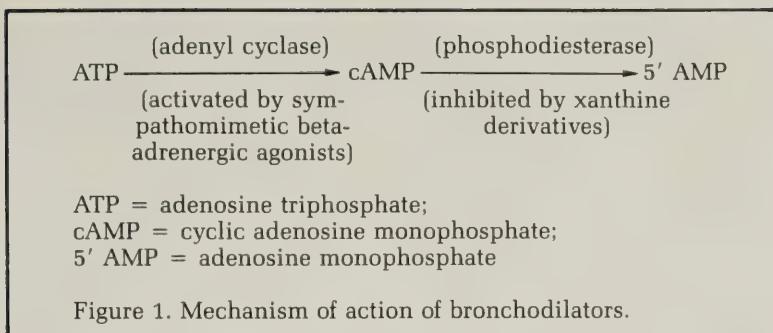


Figure 1. Mechanism of action of bronchodilators.

move in a wave-like manner to help remove accumulated debris and secretions. They also inhibit mast cell degranulation which, in turn, reduces the release of histamine and other bronchoconstricting substances. All of the above activities are helpful in alleviating symptoms of asthma.

Xanthine Derivatives. The xanthine derivatives (i.e., aminophylline, dyphylline, oxtriphylline, theophylline) inhibit the activity of another enzyme, phosphodiesterase (Figure 1). This enzyme is normally responsible for degrading cAMP by breaking its cyclical chain. Blocking its action results in increased cellular concentrations of cAMP. The higher the level of cAMP, the more completely the cell (in this case, bronchiolar smooth muscle) relaxes. The net effect is relaxation of bronchioles and more efficient air flow. Theophylline derivatives are not effective when given by inhalation.

Rationale for Combining Bronchodilators. Though the actions of sympathomimetic amines and xanthine derivatives are additive, there continues to be controversy over whether fixed combination products containing a xanthine derivative (e.g., theophylline) and a sympathomimetic amine is beneficial. Because of variations in the rate of metabolism of theophylline, its dose should be individualized to obtain effective bronchodilation. This is not possible with fixed combination products.

A person who metabolizes theophylline rapidly would receive a subtherapeutic dose when he takes a fixed dose of a theophylline/sympathomimetic amine combination product. If the number of doses is then increased to provide an effective theophylline dose, the dose of sympathomimetic amine may be excessive and cause adverse effects. The individual who metabolizes the-

ophylline slowly could receive higher than normal blood levels of this drug. To titrate the individual to the proper theophylline dose may result in a subtherapeutic dose of the sympathomimetic amine.

A final decision on the continued OTC marketing of combination products containing theophylline will be made in the future. The use of theophylline as a single ingredient is restricted to prescription products only.

It has been popular to combine sympathomimetic amines and xanthine derivatives with CNS depressants such as barbiturates or antihistamines. Barbiturates such as phenobarbital counteract bronchodilator-induced CNS stimulation. Antihistamines antagonize the action of histamine and possess anticholinergic actions. Some asthmatics may worsen because of drying of respiratory secretions. Combination products containing barbiturates or antihistamines are under close scrutiny, and their continued marketing is questionable.

Current Status of OTC Bronchodilators

Bronchodilators appropriate for self-administration were part of the extensive OTC product ingredient safety and efficacy review in the 1970's. The panel of experts that reviewed the drugs reported its findings to FDA. FDA, in turn, published its Final Monograph on these agents in October, 1986.

The advisory panel's recommendations and FDA's conclusions are listed in Table 1. As noted from the table, the panel and the agency differed in their opinions on many of the ingredients.

To review, the Category I classification means that the drug has sufficient evidence of safety and efficacy

TABLE 1

| OTC Bronchodilator Classification* | | |
|------------------------------------|-------|-----|
| Ingredient | Panel | FDA |
| Belladonna | II | II |
| Ephedrine | I | I |
| Epinephrine | I | I |
| Euphorbia pilulifera | III | III |
| Metaproterenol | ** | ** |
| Methoxyphenamine | I | II |
| Pseudoephedrine | II | II |
| Theophylline | I | II |

*Category I: safe and effective;
II: unsafe and/or ineffective;
III: safe, but requires additional study to prove effectiveness for OTC use.

**Drug was not reviewed by the OTC advisory panel. See text.

for OTC availability. Category II denotes that the drug is either unsafe or ineffective for the intended indications. Category III means that the drug is safe and that there is some, but insufficient, evidence that it is effective. Thus, additional time is needed to perform clinical studies necessary to establish efficacy.

Category I Bronchodilators. Aerosolized **epinephrine** preparations have been available without prescription since the 1930's. The drug has accumulated a good safety record throughout this period. Most reports of potential toxicity have been raised not because of epinephrine per se, but because of the chemically-related prescription drug, isoproterenol. This drug has caused increased airway obstruction in some patients.

It is important to note that the majority of toxicities to isoproterenol inhalation originated in the United Kingdom and Australia. These preparations contained a concentration of drug five times greater than that used in this country.

FDA has stated that it is unlikely that observations made for isoproterenol would be extrapolated to OTC use of epinephrine aerosols. Epinephrine, as well as its bitartrate and hydrochloride salts, is a safe and effective bronchodilator for self-administration via inhalation.

Pharmacologically, epinephrine stimulates both alpha- and beta-adrenergic receptors. As a result of alpha agonist activity, it causes localized constriction of blood vessels in the lungs. This limits systemic absorption of the administered drug, and in theory, could also limit effica-

cy of inhaled bronchodilators by decreasing drug passage into the lungs. In practice, however, small doses of inhaled bronchodilators have repeatedly been shown to be as effective as, or more than, larger doses given systematically.

Ephedrine has a slow onset of action, usually requiring 25 to 30 minutes. Activity peaks in one hour and usually persists for 2 to 3 hours.

The drug is both a direct and indirect acting sympathomimetic amine. It stimulates adrenergic receptors directly, and also causes norepinephrine release from its storage sites.

The FDA advisory panel that reviewed it concluded that ephedrine is a less effective bronchodilator than epinephrine, and its usefulness is limited to milder forms of asthma.

Metaproterenol: A Controversial Drug

One of the more interesting events of recent drug history was the "on-again, off-again" OTC status of metaproterenol. In an unprecedented action by FDA, the agency changed metaproterenol from its prescription-only classification to OTC status without review by an OTC advisory panel.

FDA reported in October, 1982, that metaproterenol had been marketed under an approved New Drug Application (NDA) for years as a prescription drug in a pressurized metered-dosage inhalation form. Reports indicated that the substance was safe and effective when used according to directions. Consequently, metaproterenol would be classed in Category I. Its manufacturers quickly responded by changing the package labeling appropriately and introducing their products (i.e., Alupent and Metaprel) to the OTC market.

There are two methods to shift drugs from prescription-only to OTC status under the current Food, Drug, and Cosmetic Act. First, manufacturers can initiate the process via an NDA, as was the case with ibuprofen and some diphenhydramine products.

Second, an FDA/OTC advisory panel can initiate the action. If the Agency agrees, the drug can be shifted. This was the process that brought OTC status to Afrin and the topical hydrocortisone products.

The shift of metaproterenol to OTC status followed neither process. Rather, it was a unilateral action initiated by FDA. FDA stated that metaproterenol was more effective and safer than available OTC bronchodilators, and that the conversion of metaproterenol inhaler products to OTC status would "...improve the overall quality of the OTC drug therapy available to persons suffering from asthma," and "...it would be in the best interest of the public health for this improvement to be effective immediately rather than awaiting publication of a final monograph for OTC bronchodilator drugs, an event that might not occur for several years."

Within a few months, OTC sales of these products approached the total prescription sales for the previous year. Some argued that this activity showed that the drug was being abused. Others countered that it was the result of supplying the marketplace with an item that had not previously been available over-the-counter, whereas its distribution as a prescription item is mainly replacement of stock already on hand. In any event, OTC product sales of metaproterenol stirred considerable controversy.

FDA soon began receiving letters criticizing both the agency's decision to move the drug OTC, and its failure to follow its own prescribed regulations. The agency responded by reconvening its Pulmonary-Allergy Drugs Advisory Committee (for prescription drugs) and soliciting its opinion. This committee reviewed documentation that was available and heard comments from proponents and opponents. It then voted four-to-three to recommend that FDA rescind its decision to permit OTC marketing.

In June, 1983, only eight months after it had shifted metaproterenol inhalers to OTC status, FDA announced that it would no longer permit such marketing. Metaproterenol reverted back to prescription-only status.

What really happened? Many tales abound! One has it that physicians rallied against the action. Another suggests that manufacturers of other OTC aerosol bronchodilator products wanted to protect their own market share. Still another suggests

that manufacturers of other prescription aerosol products claimed this decision was unfair since their products were not treated the same way.

In March, 1986, FDA announced that its Pulmonary-Allergy Drugs Advisory Committee would review the safety issues on whether albuterol, isoetharine, isoproterenol, and metaproterenol inhalers should be transferred from prescription-only to OTC status. The committee asked for comments from the industry and professions.

The response from physicians and organized medicine concerning such shifts has been generally negative due to, in their opinion, the need for close patient monitoring. Representatives of pharmacy groups have been in favor of the shifting, but only if bronchodilator inhalers became the initial entry into the "third class" of drugs, i.e., drugs available only from a pharmacist. FDA, at this time, does not have the authority to create such a class under the current Food, Drug, and Cosmetic Act. A change in the two-class distribution system would require an amendment by Congress to the Act. Nonetheless, in October, 1986, FDA announced that metaproterenol would not be shifted to OTC status.

Overview and Consumer Advice

Asthma, like diabetes, is unique in that it is not self-diagnosable, but once a physician has diagnosed the condition, it is self-treatable with OTC bronchodilator drugs. However, it is extremely important that asthma is first diagnosed by a physician.

Category I antiasthmatic product ingredients have been safely and effectively used for self-treatment of asthma for many years. But to maximize efficacy and minimize adverse reactions, OTC products must be used correctly. Specific information for consumers regarding the use of bronchodilators is presented in Table 2.

Consumers should understand that they must not exceed the recommended dosage. If relief is not obtained within one hour for oral products, or twenty minutes for aerosols, medical assistance should be sought immediately. To delay could result in worsening of symptoms, and lead to a potentially fatal outcome.

TABLE 2**Consumer Advice for Using Bronchodilators**

- Do not continue to take this medication and call your doctor immediately if symptoms are not relieved within 1 hour (for oral medication) or 20 minutes (for inhalation), or they get worse.
- This product may cause nervousness, tremor, sleeplessness, nausea and loss of appetite. If these symptoms persist or become worse, call your doctor.
- Do not use this product if you have high blood pressure, heart disease, thyroid disease, diabetes, or difficulty in urinating due to an enlarged prostate gland, without your doctor's permission.
- Do not take this product if you are taking a prescription product for high blood pressure or depression, without your doctor's permission.
- Do not give this product to children under the age of 12 (oral forms) or 4 (inhalation forms) without your doctor's permission and supervision.
- Carry a list of your asthma medications where it can easily be found by anyone helping you in case you have a severe attack.
- Do not take any other nonprescription medicine, for any purpose, without your doctor's permission.
- Do not use this product if you have ever been hospitalized for asthma, or if you are taking any prescription drug for asthma unless you have your doctor's permission.
- Do not use this product unless your doctor has told you that you have asthma.

The proper technique for administering aerosol inhalers is presented in Table 3.

There is a warning on the labeling of OTC products containing sympathomimetic amines advising asthmatics who have heart disease, hypertension, diabetes, thyroid disease, or enlarged prostate not to use the products without physician supervision. Both ephedrine and epinephrine can cause cardiac arrhythmias, palpitations and tachycardia, and worsen the patient's condition. The drugs are vasoconstrictors and can elevate blood pressure, thereby aggravating hypertension. Sympathomimetic amines may elevate blood glucose levels and cause loss of diabetic control. They exert addi-

TABLE 3**Directions for Using Oral Aerosol Inhalants**

- Shake container before using.
- Exhale fully.
- Place mouthpiece well back into your mouth, and bite down gently.
- Synchronize breathing in, while squeezing the canister into the plastic adaptor.
- Release pressure on the canister and remove the plastic adapter from your mouth.
- Hold your breath as long as possible.
- Exhale slowly through your nose.
- Keep the plastic adapter clean.

tive stimulant action to thyroid hormone on the heart. Additionally, these agents can inhibit the bladder's muscle tone, leading to urinary retention. This can cause further problems for a person experiencing difficulty urinating because of the physical size of his enlarged prostate.

None of these activities significantly affects persons who do not have the listed diseases, and to place them in proper perspective, they do not always affect those who do. There is no strict contraindication against their use. The patient should check with a physician for approval to use the products.

There is a potential drug interaction between sympathomimetic amines and monoamine oxidase inhibitors (e.g., Eutonyl, Nardil). FDA requires manufacturers to place a drug interaction precaution statement on the labeling of OTCs that contain systemic-acting adrenergic bronchodilators. Monoamine oxidase inhibitors can inhibit metabolism and elevate blood levels of vasoconstrictor neurotransmitters to the point of causing hypertensive crisis. This is one of those unusual situations in which prescription beta₂-adrenergic bronchodilators would be safer than the OTC epinephrine/ephedrine products for patients who need a monoamine oxidase inhibitor.

OTC products that contain antihistamines require a warning to asthmatics to check with their physician before using the product. The only indication for OTC bronchodilators is the treatment of asthma. Again, this is a precaution, not a strict contraindication.

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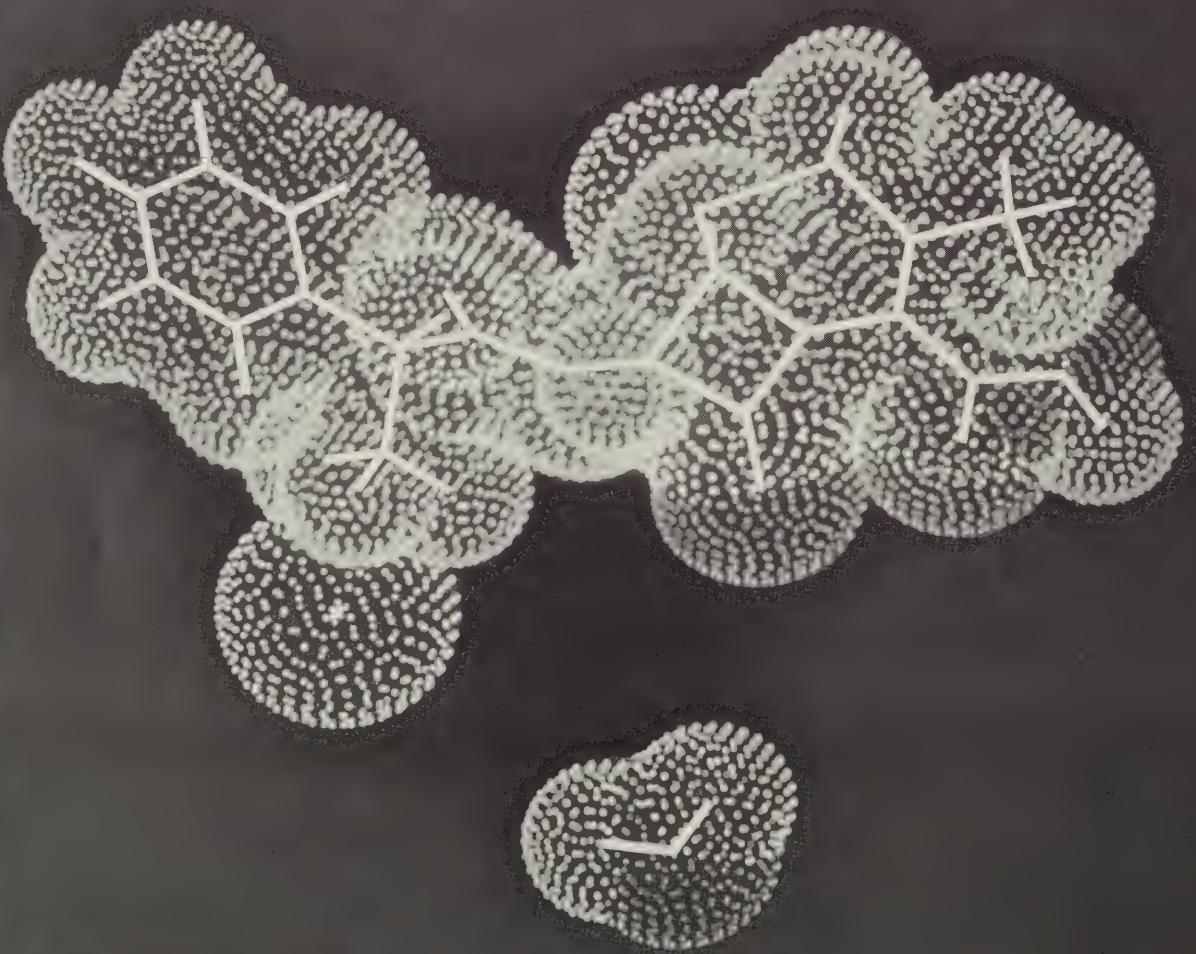
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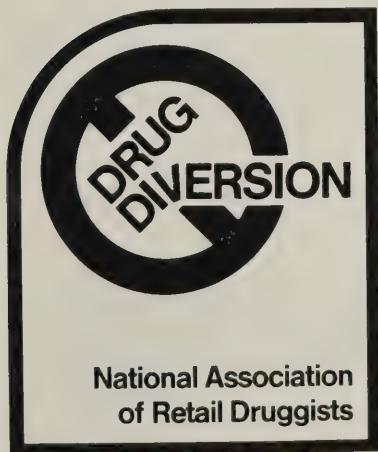
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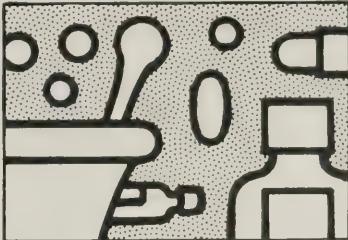
The patient education aid on the right is part of a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, MD. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

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Things You Should Know FOR YOUR GOOD HEALTH



Wise Practices for the New Year

There is no better time than the beginning of a new year to think about improving our health and developing good habits. First we should concentrate on our personal habits and then work on improving our homes and workplaces.

Quit Smoking

Negative attitudes toward cigarette smoking have become more evident in recent years throughout the country. It has been well documented that cigarette smoking is a health hazard, and that it is the largest preventable cause of death in the United States. Consider the following facts about smokers:

- Certain types of cancer occur more frequently in smokers than in non-smokers.
- Smoking is considered to be a major factor in the development of coronary heart disease.
- Smokers experience more lung diseases than do non-smokers.
- Smokers have peptic ulcer disease more often than do non-smokers.

For those individuals who are thinking about "kicking the habit" the above information should prove useful. The risks of smoking are numerous and the benefits of stopping are great.

Be Physically Fit

Numerous times pharmacists are approached by their patients with the question, "Which is the best medicine to relieve tension, nervousness and anxiety?" Many pharmacists believe that there is one; however it is not available in a bottle, box or vial. It is available to most of us free of charge, 24 hours a day. This so-called best medicine is *exercise*. Here are a few of the many good reasons for exercising regularly:

- People who begin exercise programs often sleep better, worry less, eat

less, and have more endurance than prior to their exercise programs.

- Regular exercise can play a major role in weight loss.
- Exercise appears to lessen the workload on the heart by causing the blood vessels in the heart to become larger and bring more oxygen and nutrients to the heart muscle.
- Some researchers believe that regular exercise assists in the destruction of blood clots that form and might otherwise become lodged in the heart or brain (producing heart attack or stroke).

Millions of Americans are caught up in the "physical fitness craze." Why not join them?

Medicine Safety

Too many accidental poisonings and deaths occur at home due to poor medicine safety habits. A vast number of precautions can be taken in order to reduce the likelihood of such accidents occurring to you. Here are a few for your consideration:

- Never tell a child that medicine is or tastes like candy.
- Keep all poison-containing items as well as medicines out of the reach of children.
- Never take medicine in the dark.
- Discard all medicines that are old, unlabeled, or left over from some temporary illness (such as antibiotics).
- Store medicines in their original containers. (Do not destroy the intended purpose of child-resistant containers; they were designed for a safe purpose.)

As you make your new year's resolutions keep the above-mentioned points in mind, and you will feel good about yourself and your life in the new year.

The Pharmacist and Hospice



**IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?**

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

Management of Constipation

Constipation is a problem which has many etiologies. Drugs frequently cause constipation, particularly narcotics, antacids, antihistamines, muscle relaxants, diuretics and tranquilizers. It is a difficult complaint to assess because it is not defined in concrete terms. What is normal habits for one person may differ widely from the next. When a pharmacist is dealing with the complaint of constipation, therefore, he/she must determine the extent of variation from the patient's "normal" habits before a recommendation for a laxative product can be made.

Other factors which may affect the pharmacist's decision for a laxative should include the patient's symptoms and the duration of those symptoms. Have dietary measures been tried or is lack of exercise a consideration? Does the patient's drug history add to the problem? If so, could another medication be used? Additionally, current and/or past use of laxative products is important information to obtain.

Before a laxative product is recommended, there are certain steps which can be taken which can be done to prevent constipation from occurring. There is an established relationship between dietary fiber and proper

or normal bowel activity. Fiber holds water in the fecal content, making stools softer, bulkier and heavier. This type of stool content tends to pass through the colon more rapidly. In general, a diet that contains several daily servings of fresh or lightly processed fruits and vegetables, fresh green salads and whole-grain breads and cereals will provide adequate fiber. If not, a bran cereal or small amounts of bran itself can be added. Prunes, prune juice, figs, raisins, rolled oats and whole wheat products are all good suggestions. Foods such as pastries, puddings, sugar, candy, cake and cheese may make constipation worse and therefore should be avoided. Unless contraindicated, the patient should be instructed to increase fluids. If the patient can establish a routine schedule with routine exercise, then this would also help to provide relief. Occasionally, despite all of these measures, a laxative will have to be prescribed.

When a product is necessary, stool softeners and bulk-forming laxatives should be tried first. Patients should be instructed to maintain adequate fluid intake with bulk laxative use, to prevent further constipation or obstruction. Sodium content needs to be considered for some patients (HTN, CHF) while sugar is a consid-

eration for others (diabetics). If a stimulant laxative is necessary, and it often is in patients receiving narcotic analgesics, it should be used with caution. Stimulant laxatives can produce gripping, intestinal cramping and possibly fluid and electrolyte loss (muscle cramp or pain, weakness, dizziness). A patient should be educated to report any unusual symptoms so that improper treatment will be corrected before additional problems occur. Occasionally, when abdominal cramps, nausea and vomiting also exist, the patient may require rectal (suppository or enema) administration of a product.

Drug Focus: *Senokot (senna concentrate)*

Senokot is a stimulant laxative containing senna concentrate. It is available in several product forms including granules, tablets, suppositories and syrup. It is available with a stool softener (Senokot-S) and also with a bulk-forming agent (Senokot w/psyllium). Senokot and its related products are all available without a prescription.

It is indicated for relief of constipation caused by other medicines as well as the constipation associated with the bedbound patient.

Senna concentrate encourages bowel movements by acting on the intestinal wall. It increases the muscle contractions that move along the stool mass. While this is the desired effect, it can cause problems if the laxative is misused or overused. Undesirable effects of intestinal gripping and abdominal discomfort especially on an empty stomach may occur. Taking it with food may help, but also slows the effect. Other undesirable effects can include tolerance to the drug's effects, fluid and electrolyte disturbances, malabsorption and steatorrhea. To avoid possible drug interactions, the laxative should be taken 2 hours apart from other medications.

The dose given for adults should be two tablets at bedtime or up to 4 tablets bid. Elderly and debilitated patients may require only half of this adult dose. For refractory constipation, there seems to be no maximum dose. If comfortable bowel movements do not occur by the second day, then daily dosages should be increased in increments of $\frac{1}{2}$ the starting dose until optimum dosage is established.

Senokot use is sometimes associated with an occasional pink-to-red coloration of the urine or stool. The patient should be advised of this fact. The product usually works within 6–24 hours, but occasionally requires up to three days to work.

I'm Here From The Federal Government and. . .

Everyday, hundreds of frustrated individuals throw up their hands in disgust, as a result of their inability to obtain an answer or assistance in response to a question or situation involving the federal government. Ironically, excellent thorough and courteous help is available without cost through the Federal Information Center (FIC) which was created and exists solely to provide this type of information and assistance to the public. Unfortunately, many of those needing our services are unaware of our existence.

Our services will provide you answers to questions such as:

- WHO—Processes medicare applications?
 - Assists small business financing?
 - Rents lodging in national parks?
- HOW—Do I get social security benefits?
 - Does one obtain federal employment?
 - Do I get something copyrighted?
- WHAT—Is necessary to travel abroad?
 - Protection is available for consumers?
 - Senior citizen programs are available?
 - Help exists for tax papers?
 - Federal, state or city agency can answer my questions, or solve my problems?
- WHERE—Do I go for employment information?
 - Do I go for patent and trademark booklets?
 - Do I go for consumer booklets?

If we are unable to answer a question directly, the information is researched and then conveyed to the caller. Additionally, over the years, we have also acquired extensive information in our computerized database pertaining to state and local governments, which affords us the capability to provide answers to many of these concerns.

So take advantage of the fact that we are here to serve *YOU* by calling us today with your questions, or write us at:

General Services Administration
Federal Information Center
9th and Market Streets
Philadelphia, PA 19107



See Page 25

Maryland Pharmacists Association

By-Laws

I. NAME

This Association shall be known as the Maryland Pharmacists Association and shall be abbreviated "MPhA".

II. OBJECT

The object of this Association is to bring together the pharmacists, pharmacy students and other individuals associated with the practice of pharmacy in the State of Maryland; to advance the interests of pharmacy; to enhance the professional education of all pharmacists; to provide a forum for safeguarding the public health; to promote research in the allied sciences; to seek the enactment of just laws and regulations to guide the practice of pharmacy in the State of Maryland; and to assure that all members maintain their ethics and professional obligations to the public.

III. PURPOSE

To promote the common interest of those engaged in or associated with the practice of Pharmacy in the State of Maryland.

To promote and safeguard the public health and welfare of the people of the State of Maryland.

To foster cooperation in advancing all lawful means or common purposes of its members.

To promote activities designed to improve the professionalism of its members.

To cooperate with other healthcare professionals and organizations.

To promote progress and elevate the standard of professional thought.

To afford due consideration to and expression of opinion upon questions affecting the profession and financial, economic and professional interests of its members.

To promote the proper use of drugs, medicines and healthcare devices.

IV. MEMBERSHIP

Section 1. Active Membership

Any pharmacist in good professional standing who has a valid license to practice pharmacy in any state is eligible to become an active member.

Section 2. Other Categories of Membership

The Board of Trustees shall establish other categories of membership as it deems appropriate.

V. DUES

Section 1. Dues Amount

The annual dues for each category of membership of the association shall be determined by the Board of Trustees.

Section 2. Delinquent Payments

Members who fail to pay their dues within a period specified for each category of membership by the Board of Trustees shall be notified by the executive director, and if payment is not made within a grace period, without further notice and without hearing, be dropped from rolls and thereupon forfeit all rights and privileges of membership. The Board of Trustees may by rule prescribe procedures for extending the time for payment of dues and continuation of membership privileges upon request of a member showing good cause.

VI. Meetings

Section 1. General Membership Meetings

The Association shall meet at least two times during the year at times set by the Board of Trustees. One meeting shall be known as the Annual Meeting and one shall be known as the Mid Year Meeting.

VII. BOARD OF TRUSTEES

Section 1. Duties and Responsibilities

The Board of Trustees shall provide supervision, control, and direction of the affairs of the Association, shall implement policies established by the House of Delegates, making changes if necessary within the limits of the bylaws, shall actively pursue the purposes of the Association and shall have the final discretion in

* The Constitution and Bylaws Committee has worked very hard to produce this total revision of the Bylaws. The Committee asks members to review this document which will be discussed and voted on by the House of Delegates at the Mid Year Meeting on February 7, 1988. Contact the Committee at the Office if you have any comments.

the disbursement of its funds. It may adopt such rules and regulations for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted, appoint such agents as it may consider necessary.

Section 2. Composition

The Board of Trustees shall be composed of fourteen (14) members which shall include the following officers; Immediate Past President, who shall serve as its Chairman of the Board, President, Vice President, President-Elect, Speaker and Vice-Speaker of the House of Delegates, Executive Director (Ex-officio without vote), Treasurer, six (6) elected Trustees, and one member from the Academy of Student Pharmacists of the University of Maryland School of Pharmacy.

Section 3. Terms of Office

Elected Trustees will serve for staggered three (3) year terms, two elected each year. Any Trustee shall be eligible for re-election. Election of Trustees shall be by mail ballot within sixty (60) days after nominations have been certified by the House of Delegates. The results shall be reported to the Board of Trustees by a Board of Canvassers appointed by the President. Newly elected Trustees, upon installation, immediately enter upon the performance of their duties and shall continue in office until their successors shall be elected and installed, or unless they resign, are removed, or are otherwise unable to fulfill an unexpired term.

Section 4. Meetings of the Board of Trustees

The Board of Trustees shall have regular meetings throughout the year, including a meeting at the time and place of the Annual Meeting. The Board shall meet upon call of the Chairman of the Board, or President at such times and places that may be designated, and shall be called to meet upon demand of a majority of the Board. Notice of all meetings of the Board of Trustees shall be sent by mail or other modes of transmittal to the last recorded address of the Board member at least ten (10) days in advance of such meetings. With the exception of executive sessions, where confidential issues are discussed, all regular meetings of the Board of Trustees are open to the general membership.

Section 5. Quorum

A majority of the whole Board (eight members) shall constitute a quorum at any meeting of the Board.

Section 6. Absences

If a trustee is absent from three (3) consecutive meetings for reasons which the Board has declared to be insufficient, resignation shall be deemed to have been tendered and accepted.

Section 7. Compensation

Trustees as such shall not receive any compensation for their services as Trustees, but the Board may, by resolution, authorize reimbursement of expenses incurred in the performance of their duties. Nothing herein shall preclude a Trustee from serving the Association in any other capacity and receiving compensation for such services.

Section 8. Resignation or removal

Any Trustee may resign at any time by giving written notice to the President, the Executive Director or to the Board of Trustees. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance thereof as determined by the Chairman of the Board. Any Trustee may be removed by a majority vote of the Trustees at any regular or special meeting at which a quorum is present.

Section 9. Vacancies

Any vacancies that may occur on the Board by reason of death, resignation, or otherwise may be filled by vote of the remaining members of the Board for the unexpired term.

Section 10. Indemnification

As used in this Article, any word or words defined in section 2 418 of the corporations and Associations Article of the Annotated code of Maryland, as amended from the code of Maryland, as amended from time to time, (the "Indemnification Section") shall have the same meaning as provided in the Indemnification Section.

The Association shall indemnify and advance expenses to a director or officer, of the Association in connection with a proceeding to the fullest extent permitted by and in accordance with this Indemnification Section. With respect to an employee or agent, other than a director or officer of the Association, the Association may, as determined by the Board of Trustees of the Association, indemnify and advance expenses to such employees or agent in connection with proceedings to the extent permitted by and in accordance with the Indemnification section.

VIII. OFFICERS

Section 1. Elections

The elective officers of this Association shall be active members of the Association and consist of a President-elect, Vice-president, and a Treasurer. These officers shall be elected annually by mail ballot within sixty (60) days after nominations have been certified by the House of Delegates. The results shall be reported to the Board of Trustees by a Board of Canvassers appointed by the President.

Section 2. Installation

Each officer shall take office upon installation and immediately enter upon the performance of their duties and shall serve for a term of one year or until the successor is duly elected and installed.

Section 3. Vacancies

Except for vacancies in the position of President, which will be filled by the Vice President and Speaker of the House of Delegates which will be filled by the Vice Speaker, vacancies in all other offices may be filled for the balance of the term thereof by a vote of the Board of Trustees at any regular or special meeting.

Section 4. President

The President shall be the principal elective officer of the organization and shall preside at membership meetings of the Association. In the absence of the Chairman of the Board of Trustees, the President shall preside at meetings of the Board of Trustees and of the Executive Committee. The President shall be a member ex-officio, of all committees with right to vote, and shall submit a report at the Annual Meeting of the Association.

Section 5. Vice President

The Vice President may be delegated by the President to perform duties, in the event of the President's temporary disability or absence from meetings, and shall have such other duties as the President or the Board of Trustees may assign.

Section 6. President-Elect

The President-Elect shall have such duties as the President and the Board of Trustees may assign and serves in an ex-officio capacity on all committees.

Section 7. Treasurer

The Treasurer shall keep an account of all monies received and expended for the use of the Association, shall oversee disbursements authorized by the Board of Trustees, and shall make a report at the Annual Meeting or when called upon by the President. All sums received shall be deposited in institutions approved by the Board of Trustees. Funds may be drawn only upon the signature of the Treasurer and one or more other individuals approved by the Board of Trustees. The funds, books, and vouchers under the Treasurer's control shall, at all times, be subject to verification and inspection by the Board of Trustees.

Section 8. Executive Director and Staff

The administration and management of the Association shall be in a salaried staff head, employed or ap-

pointed by, and directly responsible to the Board of Trustees. This person shall have the title of Executive Director. The Executive Director shall be the chief executive and operating officer of the Association, with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association, including employment and termination of employment of members of the staff and supporting personnel, functioning within the framework of policy aims and programs as generally determined by the Board of Trustees. The Executive Director shall have such other duties as may be prescribed by the Board. The Executive Director shall also be the Secretary to the Board of Trustees, and the Secretary to the House of Delegates. It shall be the duty of the Executive Director to give notice of and attend all meetings of the Association, to keep a record of all proceedings, to attest documents and perform such other duties as are usual for such official or as may be duly assigned.

Section 9. Bonding

At the direction of the Board of Trustees, any officer or employee of the Association shall furnish, at the expense of the Association, a fidelity bond, in such a sum as the Board shall prescribe.

IX. HOUSE OF DELEGATES (HOUSE)

Section 1. Composition

The House of Delegates shall consist of the officers of the House of Delegates, Delegates of Record, and appointed Delegates At Large.

Section 2. Delegates of Record

Delegates of Record are delegates from recognized organizations, affiliated organizations and ex-officio delegates.

Section 3. Affiliated Organizations

An affiliated organization is a pharmacy organization which has entered into an affiliation agreement with the Board of Trustees. There must be a substantial cross-membership in both the affiliated organization and the Maryland Pharmacists Association. Four Delegates of Record are allocated for each affiliated organization for a full one year term.

Section 4. Recognized Organizations

A recognized organization is that pharmacy organization, the majority of members of which are pharmacists and which carries on activities designed to encourage and promote public health and the advancement of pharmacy. Such organizations may be designated by the Board of Trustees. The designation may be terminated by the House of Delegates. Two Delegates of Record are allocated for each recognized

organization for a full one year term.

Section 5. Ex-Officio Delegates

The officers, Trustees, and the five immediate Past Presidents of the Maryland Pharmacists Association, inclusive of Board of Trustees Members, and the Officers of the House of Delegates shall be eligible to serve as Ex-Officio Delegates with vote in the House of Delegates.

Section 6. Delegates at Large

The Speaker of the House of Delegates shall appoint twenty Delegates for each meeting of the House of Delegates with the approval of the Board of Trustees upon the petition by an active member to the Speaker to be considered for such appointment. These delegates will serve for one meeting, but may be reappointed upon request by the delegates.

Section 7. Duties of House of Delegates

The House of Delegates shall be charged with the following duties and responsibilities: serve as the policy-making body of the Association; consider and implement by resolution, motion or other manner all appropriate proposals emanating from the membership; receive reports of Association Officers and Committees; adopt rules for the conduct of business; ratify the slate of officers and trustees for election and appointments to the Board of Pharmacy; and approve all proposed bylaws changes prior to a mail ballot.

Section 8. Election or Appointment of Delegates

Delegates shall be active members of the Maryland Pharmacists Association. They shall be appointed or elected by each affiliated or recognized organization for a period of one year. Delegates-at-large shall be appointed by the Speaker of the House with the approval of the Board of Trustees for each meeting of the House of Delegates. All Delegates must be certified by the Secretary of the House at least thirty days prior to each meeting.

Section 9. Officers of the House of Delegates

The Officers of the House of Delegates will consist of the Speaker, Vice-Speaker and the Secretary. The Executive Director of the Maryland Pharmacists Association shall serve as Secretary.

Section 10. General Duties of the Officers

The Officers of the House of Delegates shall arrange the programs for all meetings of the House of Delegates. The Officers shall represent the House of Delegates to the Board of Trustees and Association Committees to insure the dissemination of information and implementation of policies adopted by the House.

Section 11. Duties of the Speaker of the House

The Speaker of the House shall preside at all meetings of the House of Delegates, unless unavailable, at which time, the Vice-Speaker will preside. In the event that both the Speaker and Vice-Speaker are unable to preside, a temporary Speaker shall be elected by the House of Delegates. The Speaker shall appoint a parliamentarian to serve as an advisor on procedures and rulings. The Speaker shall appoint a Committee on Nominations, a committee on Resolutions and other committees of the House as may be necessary. The Speaker shall present an annual report for the House of Delegates.

Section 12. Duties of the Vice-Speaker of the House of Delegates

The Vice-Speaker shall preside at meetings of the House of Delegates when the Speaker is unavailable. The Vice-Speaker shall serve as Chairman of the Resolutions Committee. The Vice Speaker will assume the duties of the Speaker in the event that the Speaker cannot fulfill the duties of that office.

Section 13. Duties of the Secretary of the House

The Secretary of the House shall read all relevant communications to the House. The Secretary shall conduct and record voting in the House of Delegates when requested by the Speaker. The Secretary shall notify Committee members of the House of Delegates of their appointment and shall report and verify the credentials of all Delegates for House of Delegates sessions. The Secretary shall be responsible for the publication and maintenance of proceedings of the House of Delegates and shall distribute relevant reports to Delegates and interested parties in advance of the meetings of the House of Delegates to the extent possible.

Section 14. Meetings of the House

The House of Delegates shall meet at least twice yearly; once at the Annual Meeting and once at the Mid Year Meeting. Special meetings of the House may be called at the discretion of the Speaker, with the consent of the Board of Trustees or upon written request of one-quarter of the certified Delegates of Record. The Secretary shall report and certify the Delegates who shall compose the House of Delegates. Each Delegate shall be entitled to one vote. No Delegate shall act as a proxy for another Delegate, nor as a Delegate for more than one organization. All Association members may attend any session of the House of Delegates and shall be granted the privileges of the floor.

Section 15. Resolutions

Resolutions may be submitted to the Resolutions Committee any time prior to the last meeting of the

Committee which proceeds the Annual Meeting. In addition, Resolutions bearing the signature of two active members may be presented to the Speaker or Secretary of the House of Delegates at least 24 hours prior to consideration by the House.

The Resolutions Committee shall be appointed by the Speaker of the House of Delegates at least three (3) months prior to the Annual Meeting of the Association. The Resolutions Committee shall be chaired by the Vice Speaker of the House of Delegates and in the absence or incapacity of the Vice Speaker and individual appointed by the Speaker of the House to serve as Chairman of the Resolutions Committee.

The Resolutions Committee will submit all resolutions to the Board of Trustees for review at least (1) one month prior to presentation to the House of Delegates.

Resolutions may be adopted by the House of Delegates, defeated, tabled or referred to a committee.

Section 16. Election of the Speaker and Vice Speaker of the House of Delegates

The Committee on Nominations shall be responsible for the nomination of candidates for the offices of Speaker and Vice-Speaker of the House of Delegates. The Committee on Nominations will present a slate of at least two candidates, if possible, for each position to a session of the House of Delegates at the Annual Meeting and, if approved by the House, an election will be held at the final session of the House at which the new Officers of the House will be installed. The term of office for the Speaker and Vice Speaker is one year.

Section 17. Order of Business and Rules of Order

The Order of Business of the House shall be developed by the Officers of the House. The Rules of Order of the House shall be the version of "Roberts Rules of Order" approved by the Board of Trustees.

Section 18. Quorum

A quorum for purposes of conducting the business of the House shall be at least Twenty-five (25) Delegates and at least one Officer of the House.

X. COMMITTEES

Section 1. Presidential Appointments

The President shall annually appoint such standing, special or subcommittees as may be required by the bylaws or as the President may find necessary.

Section 2. Executive Committee

The Chairman of the Board of Trustees, the President, Vice President, President Elect, Treasurer, Speaker of the House of Delegates and Executive Director (in an ex-officio capacity) shall constitute an Executive Committee. They may exercise the powers of

the Board of Trustee when the Board of Trustees is not in session, reporting to the Board of Trustees any action taken. Four (4) members shall constitute a quorum for the transaction of business. A meeting may be called by the Chairman of the Board of Trustees or the President.

Section 3. Nominating Committee

By at least three (3) months prior to a Meeting of the House of Delegates, the President, subject to the approval of the Board of Trustees, shall appoint a Nominating Committee of at least three (3) members in good standing to nominate two (2) individuals (if possible) for each forthcoming available Trustee seat on the Board of Trustees and each office except President and Chairman of the Board. Only one (1) candidate will be nominated for Honorary President of the Association.

In addition, the Nominating Committee will annually nominate three pharmacists for each of the forthcoming available pharmacist's seat(s) on the State of Maryland Board of Pharmacy. These nominations shall be reviewed and approved by the Board of Trustees and the House of Delegates before being submitted to the Secretary of the Department of Health and Human Services for consideration by the Governor of the State of Maryland for appointment to the Board of Pharmacy.

At least two (2) members of the Nominating Committee must be either a current officer or member of the Board of Trustees or Past President of the Association. Members of the Nominating Committee may not be nominated for any position.

Section 4. Finance and Budget Committee

The Finance and Budget Committee shall consist of the Treasurer as Chairman, the Chairman of the Board of Trustees, the President, the President-elect and up to two (2) additional members in good standing. A proposed annual budget of the Association will be prepared by the Finance and Budget Committee and presented to the Board of Trustees at least three (3) months prior to the beginning of the fiscal year. Simultaneous with the preparation of the budget, the Finance and Budget Committee will conduct a salary review of the Executive Director and if appropriate will negotiate changes in the Executive Director's salary and benefits for presentation to and approval of the Board of Trustees.

XI. NOMINATIONS AND VOTING

Section 1. Nominating Process

The Nominating Committee shall be responsible for the selection and submission to the Board of Trustees the names of candidates for the offices of the Association as set forth in Article VIII, section 1 and Article VII, section 3 of these by-laws.

Section 2. Slate Approval

After certification by the Board of Trustees, the slate of candidates will be presented to the House of Delegates for final approval. Further nominations for each office may be made by the House of Delegates.

Section 3. Balloting

A mail ballot shall be submitted to the active membership by mail within 60 days after the nominations for officers have been approved by the House of Delegates. The Officers and Trustees shall be elected from the persons whose names are printed on said official ballots, the nominee for each position receiving the highest vote as certified by the Board of Canvassers to be declared duly elected. In the event of a tie vote, a supplemental mail ballot election shall be held.

Section 4. Installation

Installation of all newly elected officers of the Association will take place at the Annual Meeting.

XII. AMENDMENT OF BY-LAWS

These By-Laws may be amended by the affirmative vote of two-thirds of the delegates in attendance at the House of Delegates followed by a mail ballot by the membership with approval of two-thirds of the respondents; or a regular or special meeting of the membership called for that purpose; provided that notice to the membership, in writing, of the proposed changes be given at least 15 days before the meeting and at least 10% of the entire membership attend and then followed by a mail ballot by the membership with approval of two-thirds of the respondents.

XIII. NON-DISCRIMINATION POLICY

It is the policy of the Maryland Pharmacists Association to prohibit discrimination among individuals on the basis of sex, race, creed, national origin, age or physical or mental handicap.

XIV. AUTHORIZATION OF RELATED ORGANIZATIONS

The Board of Trustees may authorize the establishment of related organizations. These organizations do not have representation on the Board of Trustees or in the House of Delegates.

Editors Note. The revision of these Bylaws is being accomplished under the existing Bylaws which calls for two votes of the House of Delegates. Following the vote of the House at the Mid Year Meeting, the final draft will be presented to the House at the Annual Convention. Plan now to attend both meetings.

Blood Pressure Conference May 4-6

The Regions II and III High Blood Pressure Conference will be held at the Omni Hotel in Richmond, Virginia on May 4-6, 1988. The conference will be held concurrently with the conferences of the Southern Health Association, the Southern Health Commissioners, the Virginia Association of Local Health Directors, the Virginia Environmental Health Association, and the Virginia Public Health Association. Over 600 health professionals from New York to the Virgin Islands are expected to attend. Goals of the High Blood Pressure Conference include: exploring current issues in the prevention and control of cardiovascular risk factors, skill-building for health care providers, and establishing communication among public, private, and voluntary health organizations. Features include round-table "how to" sessions, a debate on "The Great Cholesterol Question," workshops, wellness activities for the individual, and much more! For more information, contact Paula Ciavarella or Joann Richardson, conference co-chairpersons, Virginia Department of Health, (804) 786-4065.

PHARMASTAT

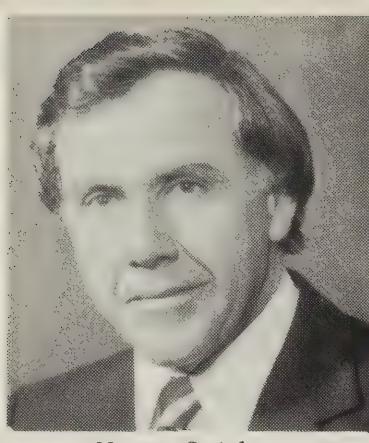
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MAY 7-13, 1988



Norman Steinberg

Join us for a fantastic seminar at sea including a vacation to beautiful Bermuda. We have arranged for a special low group fare on the spacious and beautiful Home Lines mv Atlantic.

While at sea, take advantage of a Workers Compensation seminar that could save your business a significant amount of premium year after year. Norman F. Steinberg, CPCU, will conduct a seminar that could reduce your premium cost.

Your Vacation to Include:

- Roundtrip bus transportation from Baltimore to New York.
- Six (6) nights accommodations aboard Home Lines luxurious mv ATLANTIC.
- Sumptuous breakfast, lunch and dinner daily.
- Midnight buffet.
- Nightly entertainment.
- Casinos, movies, dancing on board.

| CABIN CATEGORY | RETAIL | SPECIAL RATE | EARLY PAYMENT RATE |
|-------------------|-----------|--------------|--------------------|
| 4 - Outside cabin | \$1090.00 | \$938.00 | \$863.00 |
| 7 - Outside cabin | \$1000.00 | \$862.00 | \$797.00 |
| 12 - Inside cabin | \$885.00 | \$764.00 | \$689.00 |

Port Tax: Additional \$43.00 per person

Rountrip Bus: Additional \$25.00 per person

EARLY PAYMENT DISCOUNT is applicable if full payment is received by **FEBRUARY 26**.

All rates are per person, based on double occupancy. Space is limited and subject to availability.

DEPOSIT REQUIREMENT: \$200.00 per person will secure your reservation.

FINAL PAYMENT: If your final payment is received by FEBRUARY 26th, you will receive an additional \$75. per person off the Special Rate. Final payments received after February 26th, will pay special rate.

CANCELLATIONS: All cancellations must be sent in writing and are subject to a \$20. per person penalty. Cancellations received on or after March 21st, NO REFUND. Cancellation information insurance available and recommended.

FOR FURTHER INFORMATION, CONTACT:

PARKER TRAVEL ASSOCIATES AT (301) 252-6070
22. W. Padonia Road, Timonium, MD 21093

Enclosed is my deposit for the **Mayer and Steinberg Workmens Compensation Seminar at Sea aboard the mv ATLANTIC**, May 7-13, 1988.

NAME(s) _____

ADDRESS _____

PHONE _____ CRUISE CATEGORY _____

M&S

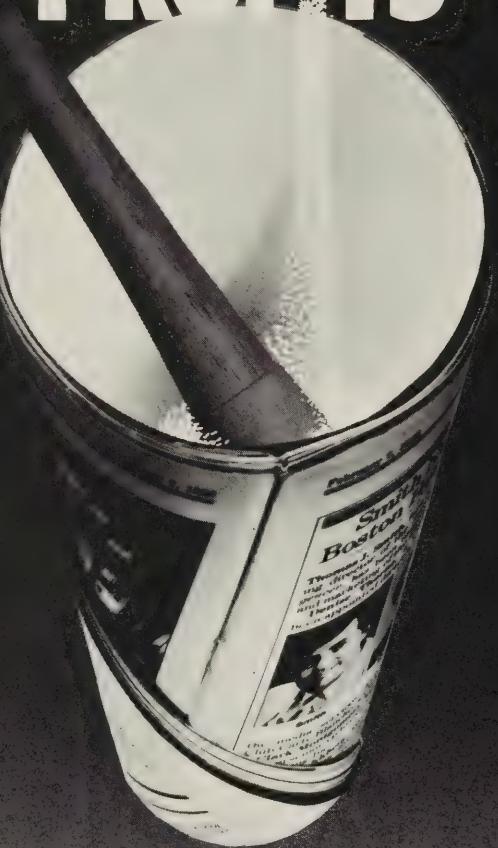
1988 TAX DATES

The following are due dates for federal and state taxes that will most likely affect you or your organization. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart. Note that if a tax is due on

| | | | |
|-----------------------|---|-------------------------|---|
| Wednesday, January 6 | <u>January 1988</u> | Monday, August 15 | FD(b) Last day for filing tax return or obtaining additional 2 month extension by individuals who obtained an automatic 4 month extension. |
| Friday, January 15 | FD(a) FD(b), FI/SI ST | | |
| Thursday, January 21 | | | |
| Monday, February 1 | <u>February 1988</u> | Monday, August 22 | ST |
| | FQ, FU, FD(c), SQ, SU Employee's statements W-2 for amounts withheld in 1987 to be furnished by employer. Employer file federal unemployment tax Form 940 for 1987. | Tuesday, September 6 | <u>September 1988</u> |
| Wednesday, February 3 | FD(a) FD(b) | Thursday, September 15 | FD(a) FD(b), FC, FI/SI, SC Last day for filing tax return by corporations that obtained an automatic 6 month extension. |
| Monday, February 15 | ST | | |
| Monday, February 22 | Forms W-2 "A" copies with transmittal form W-3 filed with Social Security Administration. | Wednesday, September 21 | ST |
| Monday, February 29 | | | |
| Thursday, March 3 | <u>March 1988</u> | Wednesday, October 5 | <u>October 1988</u> |
| Tuesday, March 15 | FD(a) FD(b) Federal and state corporate income tax return due or you must pay estimated amount due and file for automatic 6 month extension. Interest will be due on amount paid after March 15. | Monday, October 17 | FD(a) FD(b) Last day for filing tax return by individuals who obtained additional 2 month extension in August. |
| Monday, March 21 | ST | | |
| Tuesday, April 5 | <u>April 1988</u> | Friday, October 21 | ST |
| Friday, April 15 | FD(a) FD(b), FC, FI/SI, SC Federal and State Individual Income Tax due or you must pay estimated amount due and file for an automatic four month extension. Interest will be paid on amount paid after April 15. State personal property tax due. | Monday, October 31 | FQ, FU, FD(c), SQ, SU |
| Thursday, April 21 | ST | | |
| Monday, May 2 | <u>May 1988</u> | Thursday, November 3 | <u>November 1988</u> |
| Wednesday, May 4 | FQ, FU, FD(c), SQ, SU | Tuesday, November 15 | FD(a) FD(b) |
| Monday, May 16 | FD(a) FD(b) | Monday, November 21 | ST |
| Monday, May 23 | ST | | |
| Friday, June 3 | <u>June 1988</u> | Monday, December 5 | <u>December 1988</u> |
| Wednesday, June 15 | FD(a) FD(b), FC, SC, FI/SI | Thursday, December 15 | FD(a) FD(b), FC, SC |
| Tuesday, June 21 | ST | Wednesday, December 21 | ST |
| Wednesday, July 6 | <u>July 1988</u> | | |
| Friday, July 15 | FD(a) FD(b) | | |
| Thursday, July 21 | ST | | |
| Monday, August 1 | <u>August 1988</u> | | |
| Wednesday, August 3 | FQ, FU, FD(c), SQ, SU FD(a) | | |

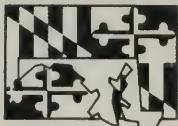
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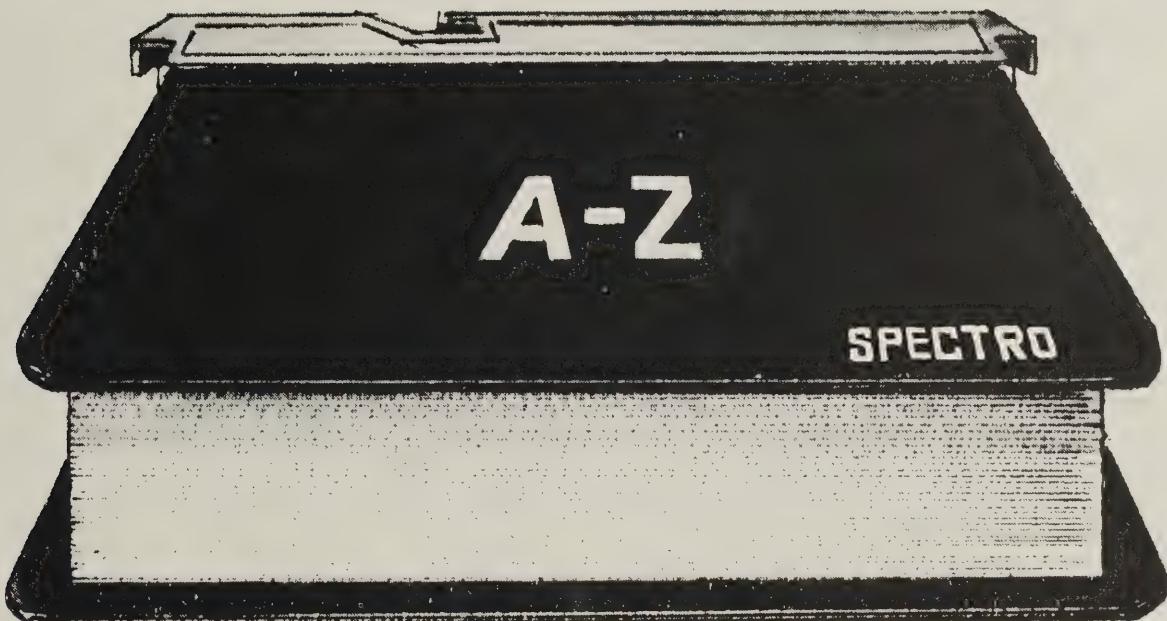


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Independent Pharmacies Are Back !!!?!

A Commentary by Jim Dickinson

Independents are back. In his best seller, "The Closing of the American Mind," Chicago professor of philosophy Allan Bloom observes "relativist" thinking among the post-1960s graduates.

That means people are unsure of right and wrong any more, and tend to see things as being "relatively" right or wrong. Any opinion is as good (or bad) as any other, and all are of equal importance (or unimportance).

You know what he means when you hear terms like, "different strokes for different folks." Professor Bloom thinks this has come about because in the 1960s the colleges stopped giving everyone enough classical studies in the liberal arts. Without that foundation, some folks don't know how to reason things out properly.

Now, I'll admit that I didn't do any classical studies, either—so when I assert that independents have turned the corner, and that the National Association of Retail Druggists has finally shown itself to be the leading pharmacy organization, there may be a temptation to dismiss this as just another equal, "relativist" opinion.

But think about the evidence.

I saw Robert J. Bolger, retiring president of the National Association of Chain Drug Stores, strolling with his wife, Helen, through the exhibits hall of the National Association of Retail Druggists annual convention in Las Vegas.

It was a record (34% bigger than last year), so I asked the head of all chains what he thought.

"It's impressive," he said, without restraint. It would have been tacky to ask for comparisons, so I left it at that. Other pharmacy convention veterans said the same thing, and did make comparisons.

The spirit among the convention attendees—the youngest-looking NARD crowd I can remember—was

buoyant and businesslike. Even the old-timers had a new glow in their eye.

But you don't go by conventions alone. It might have been the glamorous city that drew the crowds—or the weather.

Consider other factors. Consider all the floundering that's been going on in the chains—takeovers, mergers, franchising, leveraged employee buyouts . . .

Consider the unifying effects of dire, common perils like physician dispensing, mail-order pharmacy, HMOs . . .

Consider the rapid aging of the American population—any way you look at it, it has to mean a larger pharmaceutical market "pie" . . .

Consider bad service and shoddy merchandise that came to typify mass merchandisers of every kind, and indeed, consider the drug chains (like Washington-area Dart) that foundered because of their grubbiness.

Consider the NARD's slicker, fatter monthly journal and its 10% membership growth in the last 18 months . . .

Indeed, consider NARD itself. Slumped in the doldrums just over a decade ago, it has become the most important and effective of the drug-oriented associations—including the corporate-based ones.

(*I can hear the "relativists" muttering that that's only my opinion, equal to any other—but that's only their opinion!*)

NARD's recovery is proof of an ancient wisdom—that adversity is the test of strong men, and necessity the mother of invention. By the end of the 70's, government and marketplace oppression had so pressed independents that they gave NARD the energized support most associations can only dream about. Too much was at stake for it to be otherwise.

First, as the official custodian of the pharmacy heritage (the corner drug store), NARD has the important work of keeping the profession's roots alive. The graying Americans who most depend on pharmacy appreciate that, and will see to it that the modern version

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

of the corner drug store (independent-owned and operated) will have patrons wherever it can be found.

Second, NARD has attracted the best staff in the Washington drug association world.

Third, unlike counterparts in many of the Washington associations (not just the pharmacy ones), executive vice president Charles M. West has not succumbed to "Potomac fever." He attributes much of NARD's success to the grassroots and to a strong, involved executive committee and "official family," all of whom work in their own pharmacies for a living.

Fourth, NARD's leadership believes in reaching out to the grassroots pharmacist. NARD now has affiliations with 49 state associations, plus the District of Columbia and Puerto Rico—and NARD's annual legislative conference in Washington brings the grassroots pharmacy interests of state associations to the Capitol for political networking of bread-and-butter pharmacy issues.

"We will be doing more with the states in 1988," West says. "We've just been through a heavy year with burning issues in Washington, and while we're not turning down the flame on those issues, we expect to expand our activities with the states. Our first priority there will be to assure RxNet's success."

West's "burning issues," obviously, are dispensing physicians and mail-order pharmacies championed by ideological fanatics at the Federal Trade Commission who have forgotten what America is all about (they could do with a dose of Allan Bloom).

This column is not meant to sing the praises of one "relativist" association over others to which it is equal, but to observe that the independents' association currently has made itself not equal.

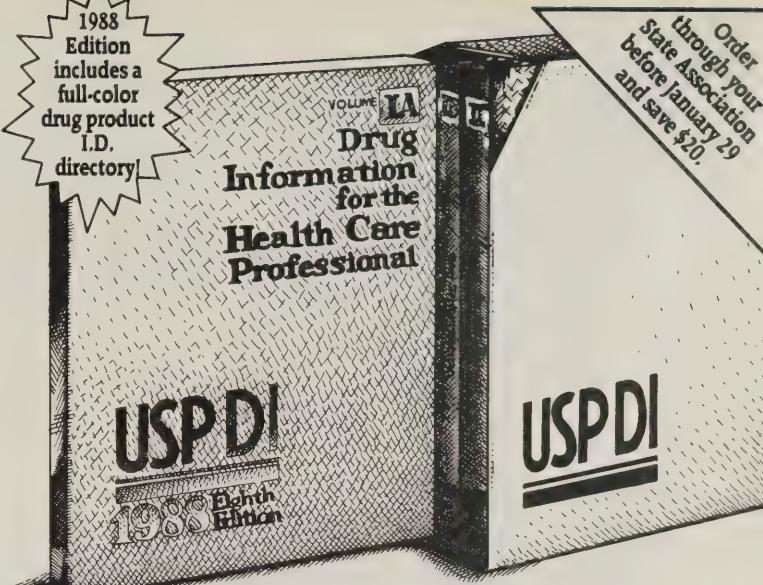
Above all, the discussion is meant to honestly reinforce the welcome news that independents are back.

To West, their re-emergence responds to a rising public demand for service, and it is in the marketplace—once the competitive playing-field is leveled (for example, by eliminating bribes to abandon neighborhood pharmacies)—that service will triumph on its own merits.

That isn't good news just for pharmacy and its unequal heritage. It's good news for America as well.



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Pharmacists Are Urged to Watch for Steroid Prescription Misuse

Reprinted from FDA Consumer

by Dori Stehlin

When it comes to illegal steroids, big muscles mean big business. The black market in steroids is estimated at \$100 million a year, according to FDA.

But for the athletes who take these drugs to enhance athletic performance and muscular appearance, it's a dangerous business. Steroids can cause numerous side effects, including liver cancer, stroke, and congestive heart failure.

To shut down this black market, four federal agencies have combined their efforts. And their work is paying off.

Joint investigations by the Department of Justice, the FBI, the Customs Service, and FDA recently resulted in a 110-count indictment charging 34 people, including a former Olympic athlete, with a complex conspiracy to make, smuggle and distribute millions of dollars worth of counterfeit steroids.

According to Peter K. Nunez, U.S. attorney for the Southern District of California, in February 1986 British Olympic medalist David Jenkins, who resides in Oceanside, Calif., asked Juan Javier Macklis, a Mexican citizen who owns a pharmaceutical lab in Tijuana, to illegally manufacture the counterfeit steroids. Macklis started producing the counterfeits, using fake labels that indicated the drugs were manufactured by legitimate—or legitimate-sounding—companies. The indictment, handed down May 21, 1987, charged that Jenkins and Macklis then set up United Pharmaceuticals and, from a Tijuana hotel, solicited business, sold counterfeit drugs, and arranged for them to be smuggled into the United States.

Others indicted were charged with smuggling or distributing the drugs, and sometimes using or threatening violence. James M. Insko Jr. of Santa Monica, Calif., Robert Wantz Jr. of Las Vegas, Nev., and Leonard T. Swirda of Los Angeles tortured and beat a steroid buyer who failed to pay on time, the indictment charges.

Since 1985, federal investigations have resulted in indictments, convictions and the seizure of \$7 million in illegal steroids. In one of those convictions, James Bradshaw of Los Angeles was found guilty of 21 felony counts of dispensing human and animal steroids without prescriptions. On Dec. 5, 1986, he was sentenced to six years in prison and was ordered to pay more than \$210,000 in fines and penalties. (For more information on the convictions and sentences of other dealers, see "Coming Down Hard on Steroid Pushers" in the November 1986 *FDA Consumer*.)

Not all of the anabolic steroids—as they are known to doctors—sold on the black market are produced illegally. There are FDA-approved uses for these drugs, including treatment of certain types of breast cancer, anemia caused by kidney failure, and aplastic anemia.

But steroids, which are chemical derivatives of testosterone, a male sex hormone, are potent prescription drugs that can cause a lot of unwanted changes as well.

For men those side effects can include atrophy, or withering, of the testicles, sterility, impotence, and over-aggressiveness. Men may also experience enlargement of the breasts. For women, shrinkage of the breasts can occur, as well as menstrual irregularities, growth of facial hair, and other masculinizing effects. The changes in men are usually reversible if the drugs are used for only a short time. Most of the changes in women are permanent.

In children and teen-agers, the steroids can cause the long bones to fuse prematurely, preventing the child from reaching normal height. In addition, the child can be pushed into early puberty.

The dangers from anabolic steroids are increased when the drugs are used illegally. What is known about the effects of these drugs is generally based on studies of patients receiving therapeutic doses. Athletes not only take as much as 10 times the recommended dose, but they sometimes indulge in a practice called "stacking"—that is, taking more than one drug at a time, both injectable and oral forms. No one knows what these stacked doses are doing to the athletes' bodies.

Many illegal deals have diverted legal drugs into black market channels. To stop that side of the

* Editors Note: Recently the Maryland Board of Pharmacy asked the Association to print information for Pharmacists on the growing misuse of Anabolic Steroids in response to rising trend.

problem, in mid-1986 FDA notified legitimate manufacturers and distributors of anabolic steroids that they were responsible for improving distribution controls. As a result, black-marketers may be turning more to smuggled foreign steroids and to steroids produced in underground laboratories.

Some of these illegally produced drugs may not even contain the steroids they say they do. In addition, the illegal versions may not be sterile—adding a risk of serious infections to the hazards.

Last Nov. 18, FDA issued an Import Alert that lists some of the unapproved foreign-source steroids that have been found on the domestic black market. The list will help both Customs and FDA inspectors intercept smuggled foreign steroids.

As if the risks from anabolic steroids weren't great enough, some athletes have added another drug to their black market shopping list: human chorionic gonadotropin, or HCG. Made from human placenta, this hormone is approved by FDA to induce ovulation in women and to cause the descent of the testes in young boys.

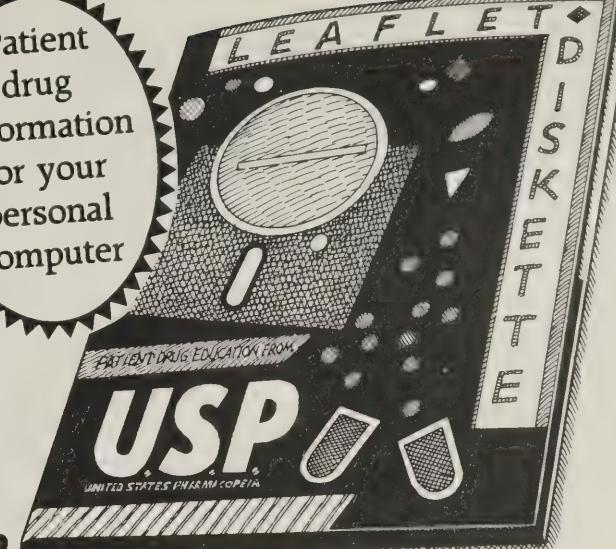
But a black market version is being sold to athletes to try to counter the enlarged breasts the steroids can cause. However, the illegal product lacks the main ingredient—HCG. In addition, it is not sterile and, therefore, may cause infections and fever.

In June, FDA, working with the Department of Justice, seized a supply of the underground-produced hormone. Because of the risk to ongoing investigations, the agency could not reveal where in the United States the seizure was made. But it said that athletes, coaches and physicians treating athletes throughout the country should watch out for the drug, which is labeled "Pregnyl Chorionic Gonadotropin for Injection. 10,000 units/vial, xxx 10ml Multiple Dose Co-Vial Organon Laboratories, Cambridge, England."

Of course, stopping the illegal market by arresting the dealers is only half the battle. As long as there are buyers, there will be new dealers to take the places of the ones who are caught. To really stop the problems, athletes must be convinced that the dangers aren't worth whatever extra edge the steroids might give them. This fall, FDA will be sending brochures with warning about steroids to high schools throughout the country. In addition, the agency is sending these schools 100,000 posters of professional wrestler Jesse Ventura telling athletes "Don't Pump Trouble . . . Stay Away From Steroids."



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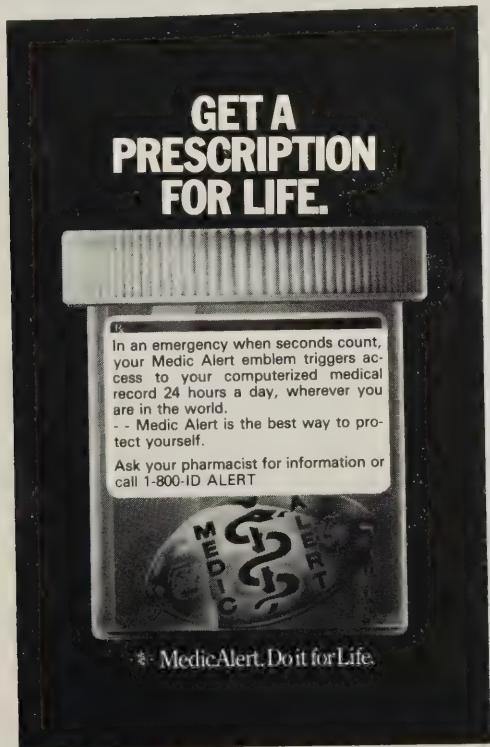
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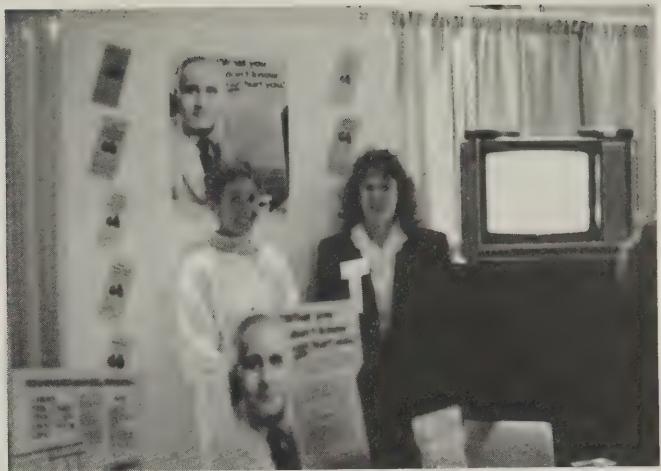
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Ceremonies were held recently at Blue Cross and Blue Shield to honor the Honorary President of the Baltimore Metropolitan Pharmaceutical Association, Mr. Stuart Baltimore. Shown (left to right) are Howard Schiff, BMPA President; Stuart Baltimore, Director BC/BS Prescription Drug Programs; Lee Ahlstrom, MPhA President; Stephen Bailey, BC/BS Senior Vice President for Group Business; and David Banta, MPhA Executive Director.



Because of the success of the public service campaign sponsored by MPhA, USP and WBAL-TV and Radio, "What you don't know can hurt you," the Association exhibited at the annual convention of the National Council on Patient Information and Education (NCPIE). Madeline Feinberg (left), Chairman of the MPhA Board and Alice Kimball, USP Director of Professional Affairs answered questions about the campaign.



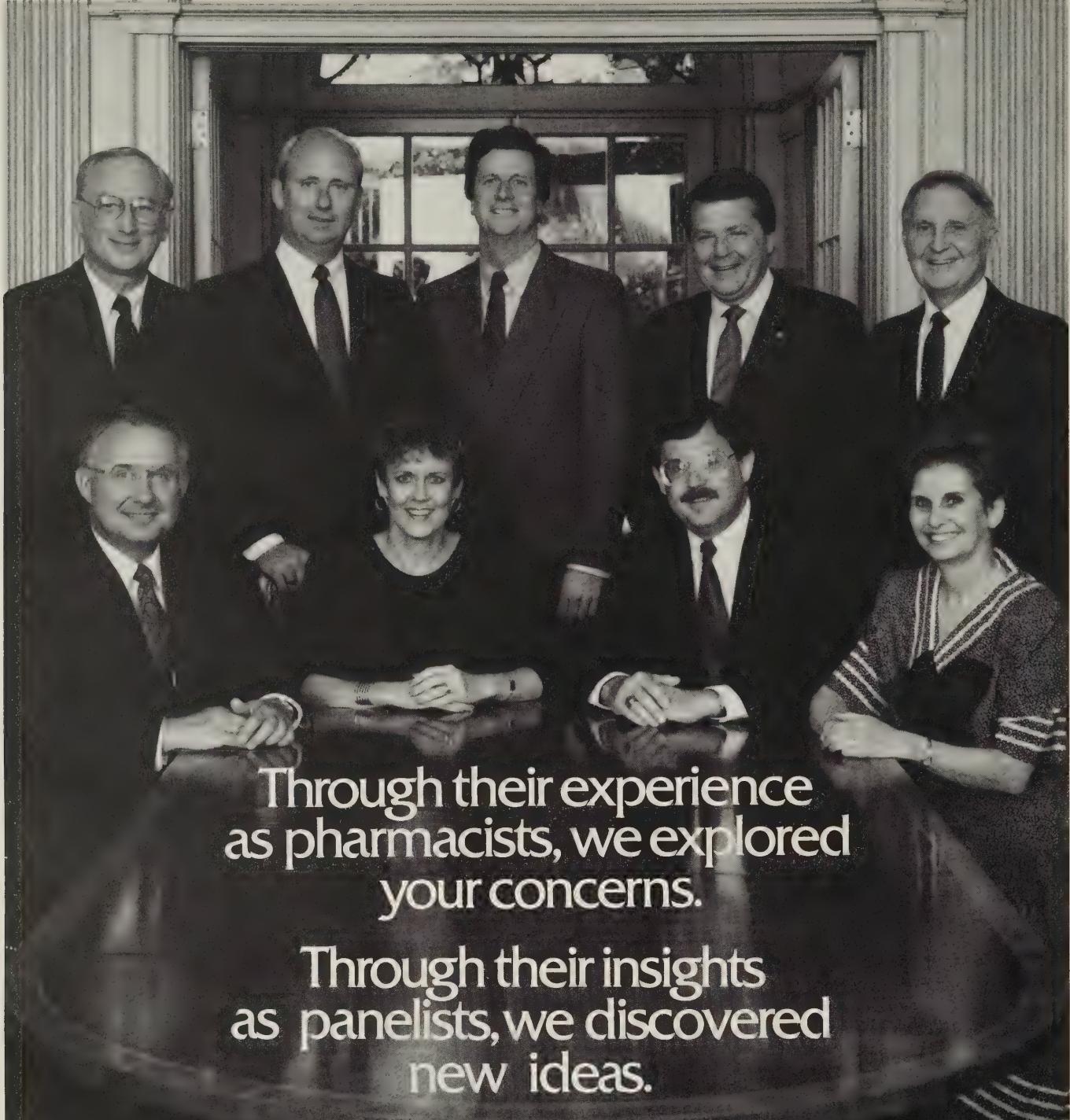
Pharmacist James Dederer (right) received the Pharmacists Against Drug Abuse, Pharmacist of the Year Award at the White House from First Lady Nancy Reagan and PADA President Herb Browne.



The BMPA held its Annual Meeting at the Pikesville Hilton to elect and install the new Officers and Executive Committee. Installing Officer Charles Spigelmire congratulates out-going BMPA President Howard Schiff (left) and incoming BMPA President Paul Zucker (right).



Charles Schmidt, Marketing Consultant for the Prescription Network of Maryland explained that the Network was very close to finalizing a new contract with Care First HMO using the NDC technology. Several other HMO's and third parties have expressed a similar interest and he continues to pursue these on behalf of Maryland Pharmacists.



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Through their insights
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Standing Left to Right:

Jack R. Cole, Pharmacist
Dean, College of Pharmacy
University of Arizona
Tucson, AZ

Reed Rosling, Pharmacist
Vice President, Hospital Sales
Bergen Brunswig Drug Company
Orange, CA

Thomas M. Ryan, Pharmacist
Vice President, Pharmacy Operations
Consumer Value Stores
Woonsocket, RI

William G. Thien, Pharmacist
Vice President
Health Services & Pharmacy Operations
Walgreen Drug Stores
Deerfield, IL

Darwyn J. Williams, Pharmacist
President
Williams Drugs Inc.
Webster City, IA

Seated Left to Right:

John H. Vandel, Pharmacist
President
Vandel Drugs, Inc.
Torrington, WY

Marily Rhudy, Pharmacist
President
Continental Pharmacy, P.A.
Topeka, KS

Thomas R. Temple, Pharmacist
Executive Director
Iowa Pharmacists Association
Des Moines, IA

M. Patricia Lee, Pharmacist
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*Not pictured: Bernard Mehl, Pharmacist, Director of Pharmacy Mount Sinai Hospital, New York, NY
John J. Piccoro, Jr., Pharmacist, Associate Director Clinical Services Chandler Medical Center, Lexington, KY*

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- Jan. 21 (Thur.)—PG/MC Program—"Therapy with ACE Inhibitors"
- Jan. 22-24—Ski Weekend Getaway, Binghamton NY
- Feb. 7 (Sun.)—MPhA MID YEAR MEETING—ANNAPOLIS HILTON
- Feb. 14 (Sun.)—Eastern Shore Association Dinner—Federalsburg
- Feb. 17 (Wed.)—AZO Evening Seminar
- April 19—Baltimore VA 5th Annual Conference on Therapeutic for the Elderly
- Mar. 13 (Sun.)—BMPA Annual Dinner Dance
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THE
MARYLAND
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Prevention and Treatment of Pressure Sores

—Thomas A. Gossel
—J. Richard Wuest

The Pharmacist and Hospice: The Living Will

—Diane White
—Lynda H. Oderda
—Ilene H. Zuckerman

MPhA Public Service Project Survey Results

Physician Dispensing and the Public Interest: A Commentary

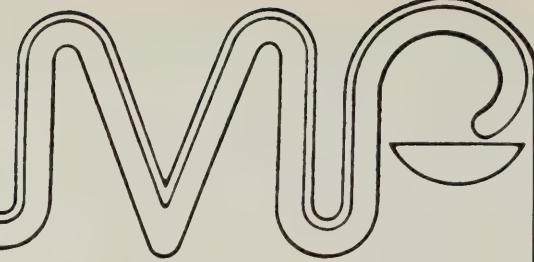
—Jim Dickinson

Taxes: Points to Consider for YOUR Pharmacy

—James R. Talley

THE MARYLAND PHARMACIST

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BALTIMORE MARYLAND 21201
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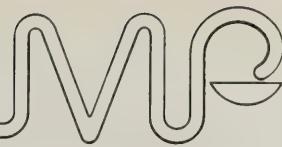
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GUEST PRESIDENT'S MESSAGE

Since 1974, federally-financed patients in skilled nursing facilities have had their therapeutic regimen reviewed, at least monthly, by a pharmacist, a function that has been found both economically and clinically effective by the Comptroller General. There were some guidelines, revolving around the number of drugs administered daily (6.2) and the number of recommendations a pharmacist ought to make (five) and other, similar and somewhat simple measures.

Some time ago, the Health Care Financing Administration proposed that this function could also be performed by nurses (presumably, because that would be cost-effective). A storm of protest arose, led by nursing who *wanted* pharmacists to continue in this function. Concerted and joint action by national Pharmacy organizations, with a major effort by the Maryland Pharmaceutical Association, led to a reversal of this proposal. Then followed a major report by the Institute of Medicine, which looked at the care offered to our elderly citizens in many nursing homes—and found it wanting in many respects.

October 16, 1987 may well be a fateful day for American Pharmacy, its practitioners, and the elderly of the United States. It is the day when new federal regulations were proposed (Federal Register, Vol. 52, No. 200, October 16, 1987). If these proposals are accepted, and all indications are that they will:

1. The number of patients to receive pharmacy consultant services will increase dramatically.
 - ALL* patients, not only federally-financed patients, will have the right to have their regimen reviewed by a pharmacist.
 - In addition, not only will residents in skilled nursing facilities be covered by that service, but so will residents in ICFs.This will mean that, effectively, the number of elderly included will increase from approximately 250,000 to approximately one million or more.
2. More importantly, the review will have to proceed in an entirely different and much more sophisticated mode. Numbers are out. Outcomes, both negative and positive, are in. An important feature of these proposed regulations is the use of objectively measurable standards that describe desirable, positive outcomes to be achieved by a facility, and negative outcomes to be avoided.

Two of the new standards will serve as examples.

Standard: Drug Therapy

The facility must ensure that each resident's drug regimen is free of:

- (1) Unnecessary drugs
- (2) Unnecessary dose levels;
- (3) Undue adverse consequences; and
- (4) Significant medication errors or significant medication error rates

Standard: Antipsychotic Drugs

Based on comprehensive assessment of a resident, the facility must insure that:

- (1) Residents who have not used antipsychotic drugs are not given these drugs unless a physician certifies that antipsychotic drug therapy is necessary to treat a specific condition; and
- (2) Residents who use antipsychotic drugs receive gradual dose reductions drug holidays, and behavioral programming in an effort to discontinue these drugs.

Pharmacists, of course, will have to help establish the criteria and monitor outcomes, a welcome expansion of the existing consultant activities.

These new efforts on behalf of our elderly citizens, coupled with efforts to reimburse for drugs for ambulatory elderly and the realization of the National Institute on Aging that data are needed on drug action in elderly with multiple pathology receiving multiple drugs opens a whole array of opportunities for new pharmacy services. Pharmacy services that should ultimately be extended to the dramatically growing home care sector. Are we ready?

Peter P. Lamy, Ph.D.

Former Honorary President

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CONTINUING EDUCATION FOR PHARMACISTS

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION

VOL. V, NO. 1

Prevention and Treatment of Pressure Sores

by Thomas A. Gossel, R.Ph., Ph.D.

Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

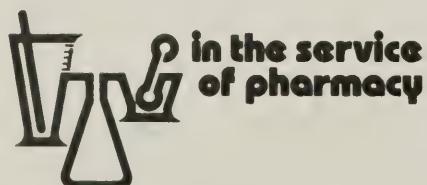
and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss the etiology and treatment of pressure sores; and
2. provide information that can be passed on to individuals who care for patients at risk of, or suffering from, pressure sores.



This continuing education for Pharmacy article is provided through a grant from

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Objectives

At the conclusion of this lesson, participants will be able to:

1. demonstrate an understanding of the etiology and pathogenesis of pressure sores;
2. identify important criteria for preventing pressure sores;
3. exhibit knowledge of the major complications and contributors to the morbidity of pressure sores;
4. select from a list of drugs, those that are used for a specific purpose, and identify the uses and limitations of these drugs; and
5. choose from a list, important points of patient advice about prevention and treatment of pressure sores.

"Pressure sores" are skin lesions that may also be referred to as decubitus ulcers, bedsores, pressure necrosis, leg ulcers, chronic ulcers, ischemic ulcers, stasis ulcers, and dermal sores. The descriptor decubitus is derived from the Latin stem *decub* meaning "laying down". The term is neither accurate nor descriptive of pressure sores. Lesions can occur in persons who are not prone.

Pressure sores are relatively common in persons with chronic diseases, especially those who reside in nursing homes. The leading candidates are individuals with spinal cord injuries, cerebrovascular accidents, and debilitating, wasting diseases. Such patients are usually elderly, but individuals of all ages can be affected.

Incidence and Cost

Surveys have shown that 3 to 4.5 percent of hospitalized patients develop one or more pressure sores during their convalescence. The incidence of occurrence is reported to be 20 to 40 percent among nursing home residents. Among paraplegics

and quadriplegics, the rate ranges from 25 to 85 percent, depending on the quality of nursing care. Seven to 8 percent of deaths in this group are attributed to complications of pressure sores, especially infection. Overall, pressure sores are associated with significant morbidity, and in some cases, mortality.

Pressure sores also represent a significant economic burden to the health care system. They may require up to 4 months to heal.

A 1966 study estimated that each pressure sore for a hospitalized patient increased the cost of medical care by \$5,000, since it resulted in considerable nursing care and extended hospitalization.

Today's cost would be expected to be higher; one estimate is \$14,000 per sore. Total expenditures to treat pressure sores in the United States may approach \$5 billion per year. It is ironic that insurance programs and other third-party providers will not pay the relatively small price for devices to help prevent pressure sores. But they will pay thousands of dollars to treat them once they develop.

Our Aging Society

The United States is becoming a society of older individuals as the average life expectancy increases. From 1970 to 1979, the rate of increase was 23.5 percent for persons over 65, compared to 6.3 percent for individuals under 65.

During the same time interval, there was a 39 percent increase in the number of Americans aged 75 and older. During the next 30 years, the number of persons 65 and older could nearly double. Many of these individuals will remain mobile and in good health; but many others will be bedridden or confined to wheelchairs — prime candidates for pressure sores.

TABLE 1

Classification of Pressure Sores

| Grade or Stage | Anatomic Involvement | Visible Signs | Treatment |
|----------------|---|---|-------------------|
| I | Superficial epidermal and dermal layers only | Skin appears red; redness does not disappear when pressure relieved | Local skin care |
| II | Extension into the adipose tissues | Skin blister or break in the skin | Local skin care |
| III | Invasion through superficial structures and adipose tissues into muscle | Full thickness of skin is lost; underlying subcutaneous tissue seen | Minor surgery |
| IV | No limit; destruction of all soft tissue with exposure of bone | Full thickness of skin is lost; muscle or bone is exposed | Extensive surgery |

Etiology

Pressure sores differ from most skin lesions in that they develop within the soft, supporting tissue of the body and then extend outward. Other dermal lesions normally begin on the skin's surface and work their way downward. They have been graded according to severity as seen in Table 1.

These sores are caused primarily by pressure exerted over a bony prominence. But this alone does not account for all lesions, because necrosis may appear at sites where pressure has not been extensive. And if pressure alone were the cause, necrosis would not extend beyond the immediate area over the prominence. Contributory factors include moisture, temperature, shear, friction, and malnutrition.

While the presence of some moisture enhances wound healing, excessive **moisture** with maceration can compromise the ability of epidermis to serve as a barrier to infection. It does this by removing lipids which normally protect the epidermis. Moisture can originate from body secretions including sweat, urine and feces. These secretions can also be sources of bacterial contamination.

The **temperature** of the tissue surrounding a bony prominence is critical. The tissue's metabolic rate, and therefore, oxygen demands, increases 10 percent for each degree centigrade rise in temperature. Thus, an increased temperature, in conjunction with tissue ischemia, would increase the tissue's susceptibility to damage.

Shear refers to skin damage that

inences are accentuated during wasting. Good nutrition is also mandatory to prevent infection and allow proper healing.

Development

Pressure sore development is orderly and well defined. Pressure applied over a bony prominence (Figure 1) is transmitted from the surface through the intervening tissues to the denser bone. The tissue's elasticity causes this force to distribute over the area in a "hammock" profile; the greatest force being over the bony prominence, and decreasing progressively outward.

A pressure gradient also exists at the surface, extending downward to the bone in a conical manner. The pressure exerted on the tissues overlaying the hip bones in a normal weight individual in a sitting position has been measured at 300 mmHg. The mean blood pressure within capillaries ranges from 12 to 70 mmHg.

Therefore, movement of blood into and out of an area of soft tissue can readily be compromised. This can lead to tissue ischemia and necrosis.

The pressure generated on an area depends on the individual's weight and surface area over which it is distributed. Muscle is sensitive to pressure, but disperses the force well.

The most significant pressure is achieved over bony prominences which are layered only with fat and skin. This includes the back of the

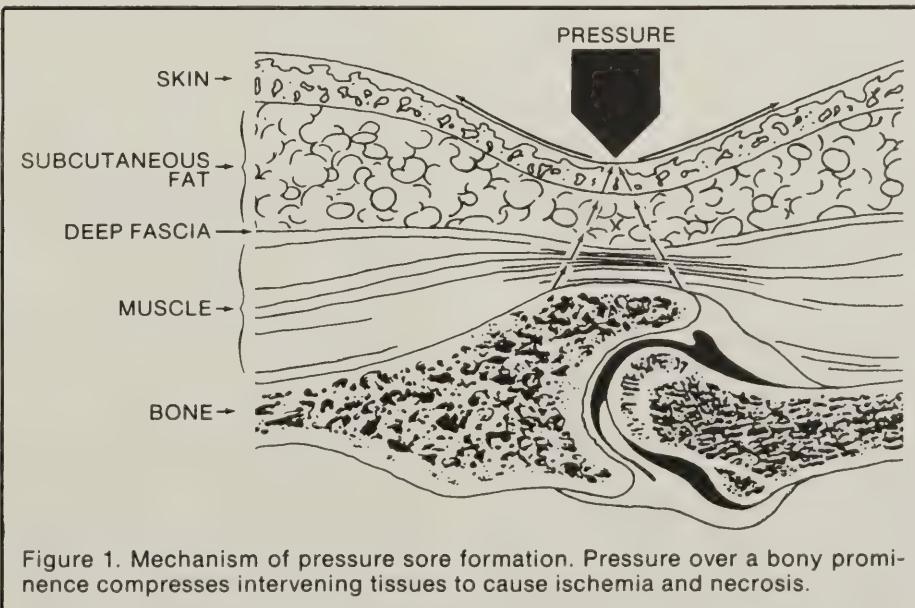


Figure 1. Mechanism of pressure sore formation. Pressure over a bony prominence compresses intervening tissues to cause ischemia and necrosis.

head, tailbone and hip area, elbows, heels, and ankles.

Over 95 percent of pressure sores are reported to occur below the waist. The pressure required to occlude blood flow depends on the patient's circulation. Individuals with compromised circulation, such as those with congestive heart disease, will be at greater risk than persons with normal circulation.

Persons with little resistance may develop lesions quickly. For example, in a severely emaciated patient, 5 to 10 minutes of pressure on a protruding tailbone against a bedpan can initiate a lesion.

As ischemia progresses, individual cells in the area continue their metabolic processes. But their metabolites begin to accumulate locally to enhance necrosis. Cells that do survive will be severely compromised and more easily injured by the forces mentioned earlier.

Nerve endings are stimulated by anoxia and local chemical irritation. In persons with normal innervation and muscular control, this incites body movement, relief of pressure and ischemia, and restores normal nutrition to the cells and removal of toxic metabolites.

The paralyzed, nerve-damaged or unconscious person cannot respond. Failure to relieve the pressure induces tissue injury. If this is allowed to continue, the lining of the capillaries may be damaged leading to blood clot formation. This, in turn, further reduces blood flow to the affected tissue resulting in cell death and ulceration. Secondary damage occurs from protein loss at the ulcer site, infection, and anemia.

Although rare, complications from pressure sores may be life-threatening. Sepsis can be severe. It may involve only underlying structures, or may be systemic.

Prevention and Treatment

Good nursing care can minimize the occurrence of pressure sores. An ounce of prevention to guard against lesions is worth many pounds of ointment and other treatments after they develop!

Manually turning the patient at least every two hours is the most effective method for preventing pressure sore development. But this may

interfere with the patient's sleep, is often uncomfortable, and can be hazardous for persons with spinal injuries. In reality, this schedule is difficult to maintain.

As with any wound, treatment of pressure sores should be based on severity (see Table 1) and associated secondary problems such as infection.

Mechanical devices are available to help relieve pressure. **Ripple mattresses** (i.e., mattresses with tubules that are alternatively inflated and deflated) appear to be effective. One study showed that patients could be maintained prone on a ripple mattress for two weeks without development of a pressure sore.

Beds that tilt and turn simulate mechanically turning of the patient. They are safer for patients with spinal injuries, and can be operated by one person. Manually turning a bedridden patient often requires two or more persons.

One device that is made specifically to prevent pressure sores consists of a rectangular box that contains numerous glass beads. This "box of beads" is covered with a monofilament polyester sheet. Warm air pressurizes the system, and the beads float on the underside of the polyester cover on which the patient lays.

Other Devices. There are many other devices on the market that are claimed to prevent pressure sores. While some of these devices do work, they can also give a false feeling of security. They are not substitutes for turning patients.

Natural sheepskin absorbs moisture from the site and reduces friction. The synthetic "sheepskins" do not provide as much protection, and neither type relieves pressure.

Foam rubber cushions and pads relieve pressure, but do not absorb moisture.

Air-filled pads and booties help distribute weight across a greater surface area, and thus, reduce pressure. However, air-filled rubber ring doughnuts should not be used because they may actually spread the tissue further apart and contribute to ulcer development.

Silicone gel cushions or pads are useful to relieve pressure and shear, but they do not reduce friction or guard against moisture.

Water beds effectively reduce pressure, but not moisture.

Semi-occlusive dressings allow passage of gas and water, but not bacteria or other solids. They permit reepithelialization of the skin and wound healing. They should not be applied to deep wounds or to those on which a scab has already formed.

Absorption dressings are flake/granule-containing products that are applied over a lesion. They absorb fluid and provide a constant moist dressing. Antacids containing aluminum hydroxide have also been used to provide a soothing, drying effect.

Besides the aforementioned items, many other concoctions have been packed into or applied around pressure sores to promote healing. These include poultices made from raw egg whites, carrots, turnips and bread; flakes of aluminum, gold and silver; chlorophyll; antibiotics, vitamins, enzymes, brine, sugar and honey. Mercurochrome, benzoin tincture, ultraviolet light and hyperbaric (high pressure) oxygen have also been employed.

Systemic treatment includes maintaining proper nutrition and treating specific infections. It has been demonstrated that pressure wound healing is enhanced in protein-depleted patients when a positive nitrogen balance is attained with a high-protein, high-calorie diet comprised of an amino acid/dextrose mixture.

Ascorbic acid is necessary for formation and maintenance of collagen, which is needed for tissue repair. Some studies have shown that geriatrics, hospitalized patients, and paraplegics have reduced blood levels of vitamin C. Several prospective double-blind studies have confirmed that vitamin C therapy aids healing of pressure sores in patients whose diets are deficient in the vitamin.

Zinc deficiency also retards wound healing. Some studies have confirmed that paraplegics with pressure sores have low blood zinc levels. Zinc supplements have been shown by some studies to enhance healing.

When systemic infections occur in patients with pressure sores, they can be a significant cause of mortality. Septicemic involvement should be vigorously treated with systemic antibiotics. However, systemic thera-

py is not effective for treating infected pressure sores *per se*; the antibiotic most likely will not reach the necrotic area in sufficient concentration.

When ulcers form and exude fluid, bacteria may colonize on the exposed dermis or subcutaneous fat. Much evidence suggests that bacteria impede wound healing. If the damaged area is extensive, a physician will remove necrotic tissue by scrapping, or using a debriding agent. Wound debridement removes dead tissue which would otherwise promote infection and slow development of granulation tissue. The latter is required for reepithelialization.

Enzyme-containing products (*i.e.*, Biozyme-C, Elase, Granulex, Santyl, Travase) have been used for debridement. Enzymes include fibrinolysin and desoxyribonuclease, papain, trypsin and collagenase. They selectively digest necrotic tissue, thereby allowing it to be more easily removed. They also aid in liquifying necrotic lesion debris. Currently, no specific product has been shown to be superior to the others. However, collagenase can digest denatured collagen fibers and is theoretically more likely to be effective.

Enzyme products may require 48 hours to show an initial effect. They are inactivated in low pH or by metallic ions. Thus they cannot be used in conjunction with topical therapy that contains acetic acid, sodium hypochlorite, aluminum acetate, iodine, silver, or other metals.

Povidone-iodine (Betadine) solution is a water-soluble preparation of polyvinyl pyrrolidone and iodine. After application, it releases iodine slowly. Its spectrum of activity includes both gram-positive and gram-negative bacteria, yeast, fungi and some viruses.

Micronized silver sulfadiazine (Silvadene) is a broad spectrum antibacterial. The drug alters bacterial cell wall membranes and is bactericidal against many gram-positive and gram-negative organisms. Unlike silver nitrate, silver sulfadiazine does not stain skin or clothing.

Hydrogen peroxide is used on pressure sores, but its mechanism of action is not entirely understood. Stimulation of granulation, oxygen production, and antimicrobial activ-

ity have been suggested for its debridement action.

The use of **topical antibiotics** should be reserved for wounds where there is a demonstrated bacterial infection. Since many infected pressure sores are colonized by more than one microbial species, a combination product containing more than one antibiotic would be preferred. Prolonged use of topical antibiotic products may lead to development of resistant strains of bacteria, and sensitization of tissues.

Dextronomer (Debrisian) is an insoluble powder of a hydrophilic dextran polymer. It may be effective when applied to extremely infected, draining wounds after the scab has been removed. While it absorbs wound drainage (up to four times its volume in fluid), cleanses, deodorizes and protects secreting ulcers, it is not effective in cleansing dry wounds.

Heat lamps have been used to dry out wounds with the assumption that heat also dilates vessels to increase local blood supply. However, drying a wound may actually decrease its rate of reepithelialization. Pressure sore lesions are already inflamed, and thus congested with blood. Heat may increase congestion at the site even more.

Overview

Pharmacists may never observe a pressure sore firsthand unless they help care for a family member or friend, or they practice in an institutional setting. The incidence of these lesions may rise as the average life span of Americans increases.

Pressure sores were once regarded as a nursing problem. Today, responsibility for preventing and treating them is shared by all members of the health care team. Pharmacists can help by passing appropriate information (Table 2) on to persons caring for others who are susceptible to, or have a pressure sore.

There are many products and therapies indicated for preventing and treating pressure sores. None of them substitutes for good nursing care.

Some products may even give a false sense of security if they are used as a substitute for moving the patient often. As stated earlier, bed-

TABLE 2

Consumer Advice on Preventing Pressure Sores

- Turn or move the patient at least every two hours.
- If the patient's bed is tilted upward, make sure there is a firm support at his feet to help prevent him from slipping down.
- Keep bed sheets fitted loosely. Lift patients when moving them. Do not pull them across bedsheets.
- Keep the patient's skin soft, clean and dry. Following washing, pat the skin dry. Do not rub it dry.
- Remove urine, pus and other secretions from around the patient quickly.
- Make sure the patient eats well-balanced meals.
- Keep patients who are confined to a wheelchair in an upright position. Do not allow them to become slouched down.
- If a pressure sore develops, contact a doctor or pharmacist as soon as possible for further advice.

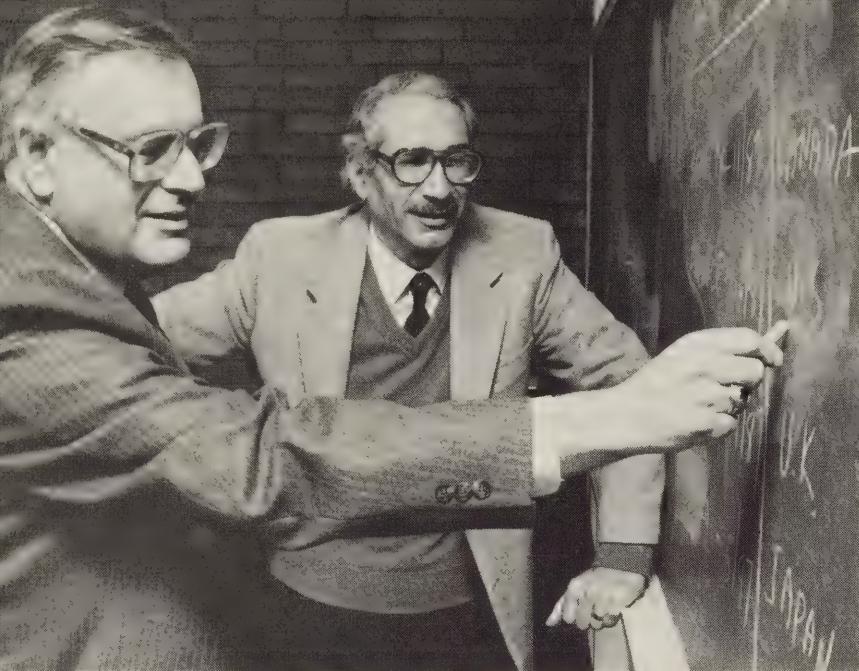
ridden and other immobilized patients should be moved at least every two hours. While this may seem difficult or impossible to manage at home, persons caring for patients should make the effort.

Pus and other foul-smelling substances should be completely cleansed away from open sores as soon as it collects. This removal serves two functions. First, its presence reduces wound healing. Second, noxious odors may reduce the time a person is willing to be around the patient, and thus, less care will be provided.

Consumers seeking medical or nursing assistance for bedridden family members may be referred to their local or county health department. Visiting nurses are often available to provide such support services.



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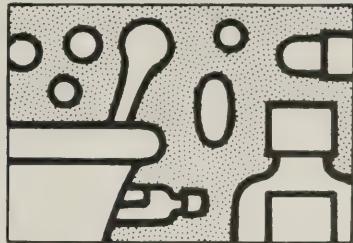


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Things You Should Know FOR YOUR GOOD HEALTH



These are Chilling Times

Winter months bring with them sledding, ice skating, snowballs, skiing, and extended periods of cold weather. Staying warm during this time of year is difficult for some people, particularly our very young and older citizens. However, long periods of exposure to cold weather increases everyone's risk of accidental hypothermia.

Hypothermia is a condition seen as a drop in deep or core body temperature (95°F or under) which can be fatal if not treated promptly. The occasional drop in surface or skin temperature, especially on the hands, face, or feet is not hypothermia.

As well as new borns and the elderly, other hypothermia candidates include people living in substandard housing and those lacking adequate nutrition. Food is the body's heat producing fuel. Without a sufficient daily intake of fuel the body's internal thermostat will be forced lower.

Symptoms of hypothermia are often not recognized by its victim which makes for an even greater danger. A hypothermia victim will show symptoms that include: (1) poor coordination or unusual clumsiness; (2)

dazed and confused behavior; (3) slowed speech; (4) feeling cool to the touch while not shivering; (5) a slow, irregular heartbeat; and (6) slow shallow breathing.

There is no single recommended treatment for hypothermia. However, if you suspect someone has developed hypothermia you should begin rewarming the individual immediately by removing the victim to a warm shelter, if possible; clothing or reclothing the victim in warm and dry garments; and seeking medical attention as soon as possible.

Some medications can effect the body's thermal control mechanisms in the central nervous system or blood vessels. Examples of the drug classes that can cause problems for those already at risk of hypothermia are phenothiazines, hypnotics, hypoglycemics, antithyroid agents, and vasodilators. Alcohol, alone or taken along with any of these medicines, can also lead to accidental hypothermia.

For more information about hypothermia and how medications may effect your ability to cope with cold weather, **ASK YOUR PHARMACIST. IT'S For Your Good Health.**

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The Pharmacist and Hospice



**IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?**

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

The Living Will

Few topics in medicine today are more complicated and more controversial than treatment of the hopelessly ill patient. One aspect of the controversy rests with a document called "the living will". Without discussion as to the right or wrongs of such a document, this newsletter will present some basic information about the living will.

The living will is the legal recognition of an individual's advance declaration directing the withholding of life-sustaining medical measures in the event of terminal illness or injury. It is a document of direction by the patient to physicians and other health care providers that no extraordinary measures be taken to prolong life once a person's condition becomes terminal. Other names for this concept are death with dignity, natural death and the right to die.

No one can accurately estimate the number of living will declarations that have been executed in the United States—both in states that give legal recognition to these documents and in those that do not. The legality of these documents is recognized in well over twenty states, and in those states a patient's doctor and health care providers are legally obliged to adhere to the dic-

tates of a living will. Moreover, they are protected from litigation when they honor the patient's wish to die. In those states with no legislative recognition, the advance declarations provide important, though not binding, evidence of the patient's wishes.

There are other formal mechanisms available to patients when their capacity for decision-making is reduced. This is especially important for the terminally ill patient whose drug therapy, disease state or pain may make competent judgment difficult. The two options which have only recently been provided for by law in several states are the appointment of a proxy (a substitute designated to speak on the patient's behalf), or an amendment to the durable power of attorney, which extends authorization to making health care decisions.

Among all the living will legislation enacted, no two laws are identical in every respect. There are, however, provisions which are basic characteristics among all of them. First and foremost, the living will (or whatever other terminology a state selects for such a document) is recognized as a legal document, legally binding to the health care providers. They provide immunity from criminal or civil liability to providers who comply with a patient's directive under the circumstances of the particular statute. The majority of states with legislation include a conscience clause which states that if the at-

tending physician is unwilling to implement the declaration, he/she must transfer the patient to another physician who will. There are only a few states which impose a penalty if such action is not taken.

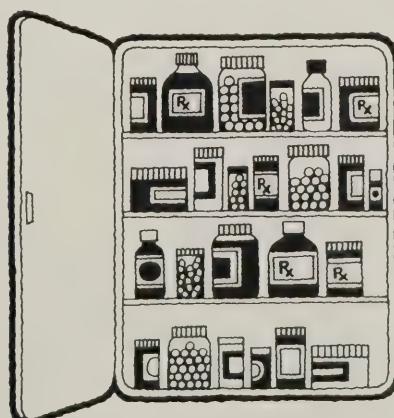
Most of the statutes contain a form for the declaration which must be either partially or wholly followed. The laws of each state establish their own procedures for executing a declaration, which requires at least two adult witnesses. Some states mandate that those witnesses cannot be family or friends, or anyone who might benefit from the patient's death.

Revocation procedures are provided for in most states, making it easy for the patient to change his/her mind at any time. Most of the laws have no time limit on the term of effectiveness. All the laws state that a patient's expressed current wishes supersede the wishes documented in the patient's declaration.

There are stated penalties for forging or intentionally destroying a patient's declaration, or for concealing knowledge of its revocation. Some states have included in their laws provision for the proxy and/or recognition of the amended durable power of attorney statutes. The laws make clear that the execution of a declaration does not constitute suicide; it has no effect on a patient's life insurance policy or health care benefits. In addition, such a statement does not give up other patient's rights (i.e. informed consent, right of privacy).

Most laws set forth the basis of qualification for implementation of the declaration. It requires a written certification of terminal diagnosis by two qualified physicians—usually resulting from examination by the attending physician and another consulting physician. Life-sustaining procedures are defined as those which only have the effect of prolonging the dying process which is imminent to the patient.

The state of Maryland *does* recognize the legality of the living will. The statutes were written into law a year ago. Those individuals interested in a copy of the law can obtain such by visiting the law library at the University of Maryland. The statutes can be found in the Health Volume of the Annotated Code of Maryland, Section 5-601, and include the statute as well as the declaration form. The number of the law library is 528-7185.



DR. DEAN LEAVITT NAMED ACTING DEAN OF UM PHARMACY SCHOOL

Dr. Edward N. Brandt, Jr., chancellor of the University of Maryland at Baltimore, has named Dr. Dean E. Leavitt acting dean of the University of Maryland School of Pharmacy while Dean William J. Kinnard, Jr. is on a year's sabbatical. A full professor, Leavitt has served as the associate dean for administration and professional services since 1976.

He received both his B.S. and M.S. in pharmacy from the University of Maryland, a Ph.D. from Purdue University and an M.B.A. from the University of Maryland College Park. Leavitt teaches pharmacy management, marketing and accounting courses in the department of pharmacy practice and administrative science.

Food and Drugs Interaction Booklet Available from APhA

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, has joined with the Food and Drug Administration, the Food Marketing Institute and the National Consumers League to produce an educational brochure for the public describing interactions between certain foods and commonly used prescription and nonprescription drugs.

The brochure is designed to help consumers decide if their diet should be changed to avoid interactions with medications they are using. The information is arranged by illness in order to make the brochure more useful. In each of these categories, examples of drugs are identified by brand and generic names and the possible interaction with specific food is explained.

In addition to specific examples of food and drug interactions, the brochure urges consumers to be aware of the dangers of mixing certain drugs with alcohol, caffeine and cigarettes.

The public may obtain a copy of the brochure by sending 25 cents and a business-size self-addressed, stamped envelope to the National Consumers League, 815 15th Street, N.W., Suite 516, Washington, D.C. 20005.

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Warner Chilcott Laboratories is ready to tackle major market changes in a way no other generics company has—by providing one of the most extensive industry catalogs available. Starting today, you can get all your generic product needs from a single source:

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The best way to meet change is to make changes.

Ask your Parke-Davis representative or local wholesaler for more information on Warner Chilcott terms of sale and services.

Convention Awards

The Awards Committee of the Maryland Pharmaceutical Association is soliciting nominations from the membership for two prestigious awards which are presented to pharmacists at the Annual Banquet. The Committee decided that more membership input into the Awards process would be appropriate. The two Awards are:

BOWL OF HYGEIA This award is presented annually through the cooperation of the A. H. Robins Co. to a pharmacist who has compiled an impressive record in the area of community service.

MphA ACHIEVEMENT AWARD This recently instituted award is given to a pharmacist who is distinguished in the area of contributions to the profession of Pharmacy.

Nominations for either of these two awards may be sent to the Awards Committee for consideration. Nominations must be in writing and should outline the qualifications of the individual for the award being considered. Nominations are kept on file each year and may be considered by the Awards Committee in future years. Nominations or inquiries about the nominating process should be sent to the M.Ph.A., 650 W. Lombard Street, Baltimore, Maryland 21201.

Convention Resolutions

The Vice Speaker of the House of Delegates, Ilene Zuckerman, also serves as Chairman of the Association's Resolutions Committee. The Committee will be meeting soon to consider issues and resolutions for the Annual Convention of the Association, June 19-23, 1988 in Ocean City, Maryland. In order to allow for greater membership participation in the resolution process which forms the basic policy making structure of the Association, the Committee is soliciting input from the membership in the form of suggested resolutions or resolution topics. Resolutions may be sent to the Association at this time with any background or supporting information necessary. They should be sent to the M.Ph.A. Resolutions committee, 650 West Lombard St., Baltimore, Md. 21201.

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—\$.02 per coupon; 500 to 1000 coupons—\$.02.5 per coupon; and batches of 1000 coupons and over—\$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.

COUPON REDEMPTION PROGRAM

Call Mary Ann at the MPhA office (301-727-0746) to receive details by mail and your first mailing packet.





Through their experience
as pharmacists, we explored
your concerns.

Through their insights
as panelists, we discovered
new ideas.

The members of our 1987 Pharmacy Consultant Panel spoke from personal experience. But their ideas and concerns spanned the breadth of our profession. We thank them for sharing their wisdom, experience and advice. Most of all, we look forward to putting their ideas to work to serve pharmacy professionals better.

Standing Left to Right:

Jack R. Cole, Pharmacist
Dean, College of Pharmacy
University of Arizona
Tucson, AZ

Reed Rosling, Pharmacist
Vice President, Hospital Sales
Bergen Brunswig Drug Company
Orange, CA

Thomas M. Ryan, Pharmacist
Vice President, Pharmacy Operations
Consumer Value Stores
Woonsocket, RI

William G. Thien, Pharmacist
Vice President
Health Services & Pharmacy Operations
Walgreen Drug Stores
Deerfield, IL

Darwyn J. Williams, Pharmacist
President
Williams Drugs Inc.
Webster City, IA

Seated Left to Right:

John H. Vandel, Pharmacist
President
Vandel Drugs, Inc.
Torrington, WY

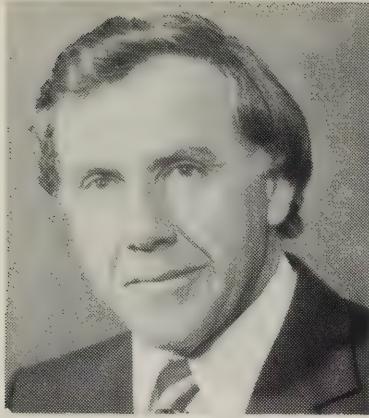
Marily Rhudy, Pharmacist
President
Continental Pharmacy, P.A.
Topeka, KS

Thomas R. Temple, Pharmacist
Executive Director
Iowa Pharmacists Association
Des Moines, IA

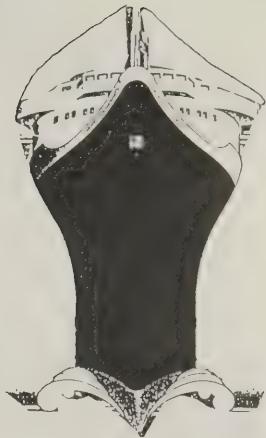
M. Patricia Lee, Pharmacist
Director of Pharmacy
UCSD Medical Center
San Diego, CA

Not pictured: Bernard Mehl, Pharmacist, Director of Pharmacy Mount Sinai Hospital, New York, NY
John J. Piecoro, Jr., Pharmacist, Associate Director Clinical Services Chandler Medical Center, Lexington, KY

Upjohn



Norman Steinberg



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MAY 7-13, 1988

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While at sea, take advantage of a Workers Compensation seminar that could save your business a significant amount of premium year after year. Norman F. Steinberg, CPCU, will conduct a seminar that could reduce your premium cost.

Your Vacation to Include:

- Roundtrip bus transportation from Baltimore to New York.
- Six (6) nights accommodations aboard Home Lines luxurious mv ATLANTIC.
- Sumptuous breakfast, lunch and dinner daily.
- Midnight buffet.
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- Casinos, movies, dancing on board.

| CABIN CATEGORY | RETAIL | SPECIAL RATE | EARLY PAYMENT RATE |
|-------------------|-----------|--------------|--------------------|
| 4 - Outside cabin | \$1090.00 | \$938.00 | \$863.00 |
| 7 - Outside cabin | \$1000.00 | \$862.00 | \$797.00 |
| 12 - Inside cabin | \$885.00 | \$764.00 | \$689.00 |

Port Tax: Additional \$43.00 per person

Rountrip Bus: Additional \$25.00 per person

EARLY PAYMENT DISCOUNT is applicable if full payment is received by **FEBRUARY 26**.

All rates are per person, based on double occupancy. Space is limited and subject to availability.

DEPOSIT REQUIREMENT: \$200.00 per person will secure your reservation.

FINAL PAYMENT: If your final payment is received by FEBRUARY 26th, you will receive an additional \$75. per person off the Special Rate. Final payments received after February 26th, will pay special rate.

CANCELLATIONS: All cancellations must be sent in writing and are subject to a \$20. per person penalty. Cancellations received on or after March 21st, NO REFUND. Cancellation information insurance available and recommended.

FOR FURTHER INFORMATION, CONTACT:

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22. W. Padonia Road, Timonium, MD 21093

Enclosed is my deposit for the **Mayer and Steinberg Workmens Compensation Seminar at Sea aboard the mv ATLANTIC**, May 7-13, 1988.

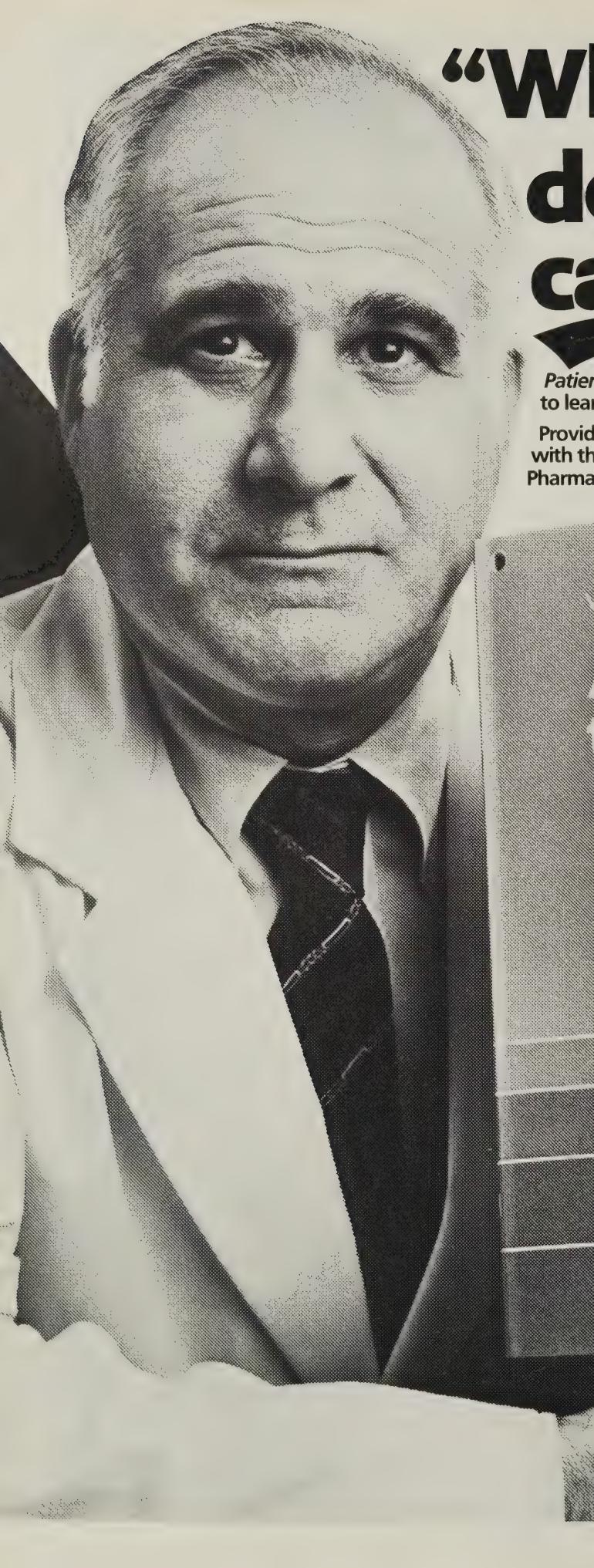
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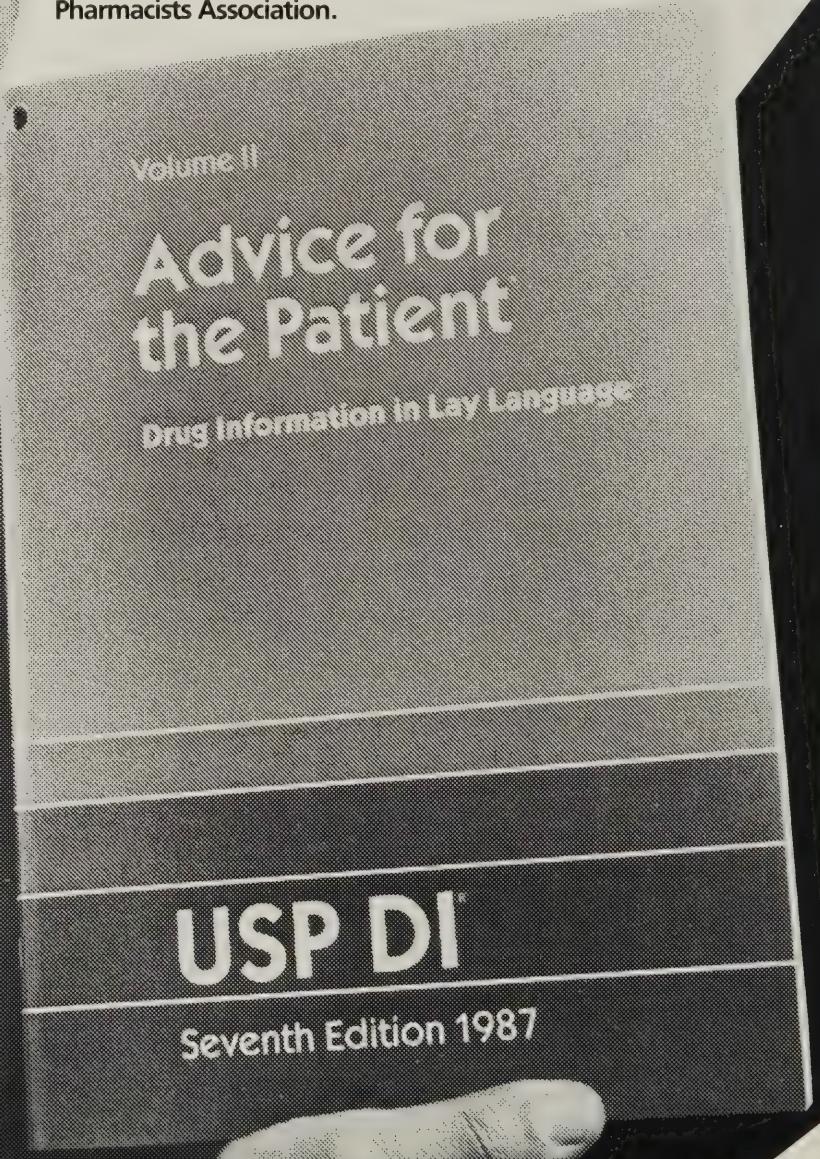
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"What you don't know can hurt you."

Ask our pharmacist about the book *Advice for the Patient*.[®] For your own safety, health, and well being, use it to learn about your medicines and how to take them properly.

Provided as a public service by the United States Pharmacopeia with the cooperation of the Maryland Pharmacists Association.



AS SEEN ON
WBAL-TV


Results of an Evaluation Questionnaire of a Public Service and Patient Education Project

Sponsored by
The Maryland Pharmacists Association
The United States Pharmacopeial Convention
WBAL—Television and Radio in Baltimore

BACKGROUND

The Maryland Pharmacists Association (MPhA), the United States Pharmacopeial Convention (USP) and WBAL—TV and Radio in Baltimore agreed to participate in a unique public education campaign designed to encourage patients to discuss prescription drugs with their community pharmacists in a statewide public service announcement campaign. In May, 1987, a complimentary copy of the "Advice for the Patient" portion of the USP's publication *Dispensing Information* was mailed to the approximately 900 community pharmacies (both chain and independent) in Maryland by USP. At the same time, a public service kit was also mailed to these pharmacies which included letters of endorsement from the three sponsoring organizations, a large display poster, a display counter card, an advertisement slick and a pad of order forms for subscriptions to the USP-DI. The promotional material in the kit featured a picture of pharmacist William Weiner, owner of Weiners Pharmacy in Baltimore, and Chairman of the MPhA's Public Affairs Committee. He is holding a copy of the "Advice to the Patient" Book with campaign slogan: "What You Don't Know Can Hurt You."

Shortly after this material was mailed to the pharmacies, WBAL—television and radio, which has substantial coverage for most of the State of Maryland, began airing a public service announcement which was produced and contributed by the station. The PSA featured Dr. Weiner displaying a copy of the publication and advising patients to consult with their Pharmacist about prescription drugs. The actual text for the PSA reads:

"Medicines. When you take them improperly, you take a risk. A risk that they won't work . . . or worse . . . that they may produce serious side effects. That's why it's so important to ask your pharmacist about your medicine. Every Pharmacy in Maryland now has a special book called "Ad-

vice for the Patient." Use it to look up the drugs you're taking. Find out what they're supposed to do and how to take them properly. When it comes to medicines, what you don't know can hurt you. A message from the United States Pharmacopeia, WBAL TV and the Maryland Pharmacists Association."

The PSA was broadcast on WBAL-TV and Radio throughout the summer of 1987 in a variety of time slots including many prime time airings. A newsrelease was sent to Maryland news media, as well as pharmacy trade press, announcing the project. WBAL-TV featured the project prominently as part of a nightly news segment. Copies of the publication and the public service kit were sent to key members of Maryland General Assembly who serve on health related committees in the state legislature. The MPhA office received many favorable comments on the project from pharmacists and the public. Some patients inquired about purchasing the publication for themselves. Pharmacies were contacted to make sure they had received the publication and the kit and replacements were mailed to those who indicated they had not received the material.

The MPhA formally launched the project with a special presentation at its annual convention in June, 1987. The project was reported in its monthly newsletter and featured in its Journal in several issues. Toward the end of the campaign, Maryland Governor William Donald Schaefer issued a proclamation recognizing the effort of the three organizations and commending the public education project. Another newsrelease was sent with a copy of the picture of the Governor, representatives from the sponsoring organizations and the publication.

The Evaluation Questionnaire

In early August, an evaluation questionnaire was

sent to the approximately 900 Maryland pharmacies participating in the public service project. The object of the survey was to determine the usefulness of the material, attitudes of pharmacists toward the project and pharmacists perceptions of patient's reactions to the material.

RESULTS

One hundred and seventy respondents, both chain and independent pharmacies, reported that they had received the material. Eighty-two reported that they had seen the public service announcement. Fifty-five indicated that they had heard the PSA on radio. One hundred and thirteen respondents said they left the book, "Advice for the Patient" on the prescription counter within view.

Ninety pharmacists reported that having the book available did serve to initiate communication between the pharmacist and the patient. A total of one hundred and forty said that the PSA kit and the book were an effective tool for patient counseling and consumer drug information. One hundred forty-one said they thought the public service campaign was a worthwhile endeavor. Of the materials provided, pharmacists indicated that the book, "Advice for the Patient" was by far the most useful portion of the PSA kit that was made available to them.

A more complete breakdown of the results is available from either the MPhA or the USP and was broken down between chain and independent pharmacy respondents.

CONCLUSION

The general impression from the sponsoring organizations and those who responded to the questionnaire was that the public service campaign was a success. It appears to have generated greater awareness of the community based pharmacist as a resource for drug information utilizing the vehicle of the availability of the USP publication. The project was unique because it accomplished more than just to provide a health related message to the public; it offered an opportunity for action by the patient. Response by the public seems to have been favorable.

PUBLIC SERVICE ANNOUNCEMENT

Comments from Responders

"Did having the book available initiate communication between you and your patients?"

INDEPENDENTS

- "Even though I always (nearly always) counsel my patients, the book was good back-up! It showed my patients I knew what I was talking about and not afraid to have it checked."

- "Is the book any good? How can I order?"
- "Enabled customers to ask questions with information in front of them, thereby eliminating the feeling of ignorance (the 'stupid' question)."
- "Whenever the patients have questions we look up the information."
- "Asked if we were selling the book. Asked questions about meds they were taking."
- "Made available a non-PDR source of information. It gave patients a respect for relationships between drugs within the same class as opposed to thinking of drugs as separate entities entirely."
- "They asked information about their medicine, and we referred them to the book."
- "Asked to help find their drugs in the book—opens discussion on their medications."
- "Questions on terminology and how to locate information in the book."
- "Patient looks thru book, then asks questions."
- "One person mentioned seeing it. No one asked any questions or otherwise seemed to care."
- "Made patients think of questions they otherwise would not have asked."
- "Side effects main concerns of patients. Frequently discussed."
- "Patients who have questions about medication or patients who I think need info due to the nature of the meds are given copies of appropriate pages of the book. (Our copy machine is behind the counter.) Our patients are always asking questions—but since ours is a small pharmacy I usually have time to talk with them in person and use the copied material as a back-up."
- "Answers to their questions—give book to patient—show where to find drug in question—then clarify their questions."
- "Questions."
- "We have had copy for several years. Has been well utilized."
- "Customers reading book asked questions."
- "Most didn't want to read immediately, but asked questions with many promises to purchase."
- "Tells patient any interaction, side effects that they wish to know. If they have seen the announcement, they may ask to see book."
- "(We had previously ordered the book and already been promoting the use of it.) The extra copy enabled us to let the patient use it and return it to us. Concept great! Need to use in areas outside Baltimore. Channel 47 or 16—Both in Salisbury."
- "Book was useful. All others in the kit of no value."
- "We are reviewing the materials ourselves."
- "My thoughts as to reaching the people most in need. Reference to the Medical Assistance patient. A mass mailing of a single page letter telling Medical assistance patients of pharmacist contact available to answer drug questions."

- “I always explain to my patients about their medications. The book helps while the patient is waiting for his (her) prescription. It gives them something to read about, esp. what he/she is taking.”
- “I use the USP DI like a priest uses his Bible—the presence of the book on the counter stimulated a lot of ‘so this is where you get your info’ or ‘you must have this thing memorized.’”
- “Questions about the book. Most saw me and wanted to know if it was me. I thought it was the greatest thing since sliced bread.” (Pharmacist whose picture was on poster)
- “Patients have asked me questions about certain medications. I referred them to the book.”
- “The USP DI is the best thing that the USP ever did for retail pharmacy.”
- “Curiosity. Availability triggered questions knowing answer was readily available.”
- “Various related drugs patients were using including OTC.”
- “It gave them more questions to ask.”
- “I had at least five patients ask for the book. All thought the 7 were free give away books.”
- “Same old ways. Think the public service campaign was too general.”
- “Let patient read while filling Rx.”
- “We have always communicated with our patients.”
- “Some patients simply started asking questions concerning the book.”
- “Explained action of the drug as well as side effects in lay (easy to understand) language.”
- “We have had the book always and are constantly suggesting to patients that they stop and take time to read it—THEY DO!”
- “Customer thumbed through to get her Rx item and then we discussed.”
- “Some patients have never asked about their medicine and like this system.”
- “Customers commented on having seen the ad.”
- “Interaction of Drugs.”
- “Made public more aware to ask questions or to ask for a more valuable reference—we’ve always had one available!”
- “But we currently consult ‘like crazy’.”
- “If I thought there were significant side effects.”
- “We counsel every patient about every prescription we fill. The DI book is useful tool in counseling patients.”
- “We make it a point to initiate communication with all patients with or without books. I am concerned that the book will diminish consultation!”
- “One interpatient led to many other inquiries—concerning pharmacy and health.”
- “Usually, I explained use of book and they asked questions on what they had read.”
- “Patients were more likely to have questions about their medications.”
- “Clarification of information available in USP DI, questions about generics.”
- “Opportunity for patient to review their medications in USP DI while pharmacist was filling Rx. Pharmacist goes over drug later with patient.”
- “The USP DI itself is not too good for my customers (mostly welfare patients who can’t read) but the book is good for the RPh’s here to help counsel patients.”
- “Had only 2 requests for book—patient remarks were ‘neutral’ to date. My opinion of program is negative.”
- “Some inquiries.”
- “We were already doing this without another reference book.”
- “Specific questions relating to proper administration of drugs.”
- “The ad campaign was not noticed by very many of our customers. However we are trying to promote it to our customers as part of our patient counseling.”
- “The patients were asking specific questions about medications.”

CHAINS

- “Patients would read the book, then patient would ask specific questions about their meds or ask me to explain certain points.”
- “Explaining side effects, how to take medications, and what medications might interact with their new medication(s).”
- “Specific medication questions.”
- “It increased customer awareness of their medication.”
- “Information is available in a library if patient is interested.”
- “Helpful to be able to give patient information to take with. Did not seem to notice much response from the public service campaign, but thought it a good program.”
- “We have time for very little of this due to heavy workload and administrative duties.”
- “Additional information about side effects and combinations with other medicines.”
- “Ask about specific drug/interaction.”
- “When a patient was seen using the book, I knew they might need additional information, so I asked.”
- “Ask more questions.”
- “In helping them look up the page numbers for the medication, it gave a chance to discuss their medication.”
- “It helped several patients; they were able to ask some questions regarding their medication.”
- “We brought it to the patient, turned to the material and both discussed it and asked the patients

to sit down and take the time to read it. Told them to ask us any questions they still had."

- "No, it did not, but I have pointed out the book to patient who wanted more information."
- "I told them to ask if they had any questions and/or offered advice. People readily look at the book. It helps."
- "Got people to start asking questions."
- "Patients asked more questions after reading through the monograph. They could be more specific in asking about side effects."
- "Regarding their new medicines especially."
- "Patients read the book and asked questions about what they didn't understand."
- "When they ask questions on their Rx's I answered them and use the book as a reference and let them read additional information."
- "Several patients looked up the drugs and initiated discussions while waiting for Rx's to be completed."
- "We have had similar books available."
- "Not much response." Probably a much better idea for independents."
- "Asked more questions."
- "Most wanted to say that they were glad to hear about the book being available."
- "They often ask questions, and we let them see book."
- "No change noticed."

Lamy Named Assistant Dean at School of Pharmacy

Dr. Peter P. Lamy, professor and director of the Center for the Study of Pharmacy and Therapeutics for the Elderly at the University of Maryland School of Pharmacy, has been appointed assistant dean for geriatrics and institutional programs at the school. He is a resident of Catonsville.

Lamy, whose book, *Prescribing for the Elderly*, was published in 1980, is the author of more than 350 publications, and is the editor of a national newsletter, *Elder Care News*. Additionally, he is on the editorial boards of *Drug Therapy for the Elderly*, the *Journal of the American Geriatric Society*, *Cardiology World News*, *Pharmacy World News*, the *Geriatric Consultant* and *Geriatric Medicine Today*.

Lamy is a fellow in the American Geriatrics Society, the Gerontological Society of America, the American College of Clinical Pharmacology and the American Association for the Advancement of Science. He is also Post Honorary President of the MPhA.

ATTENTION

—PHARMACY OWNERS AND MANAGERS— —HOSPITAL PHARMACY MANAGERS—

NEVER WORRY ABOUT FILLING YOUR PHARMACY SCHEDULE AGAIN!

PHARMASTAT, a company providing for the needs of your pharmacy is now operating in Maryland! We provide pharmacists for emergency relief, vacations, employee illness, or anytime you need a pharmacist. All pharmacists are pre-screened, and are matched to the type of computer system you are using.

When you need a retail pharmacist, you get a professional with retail management experience.

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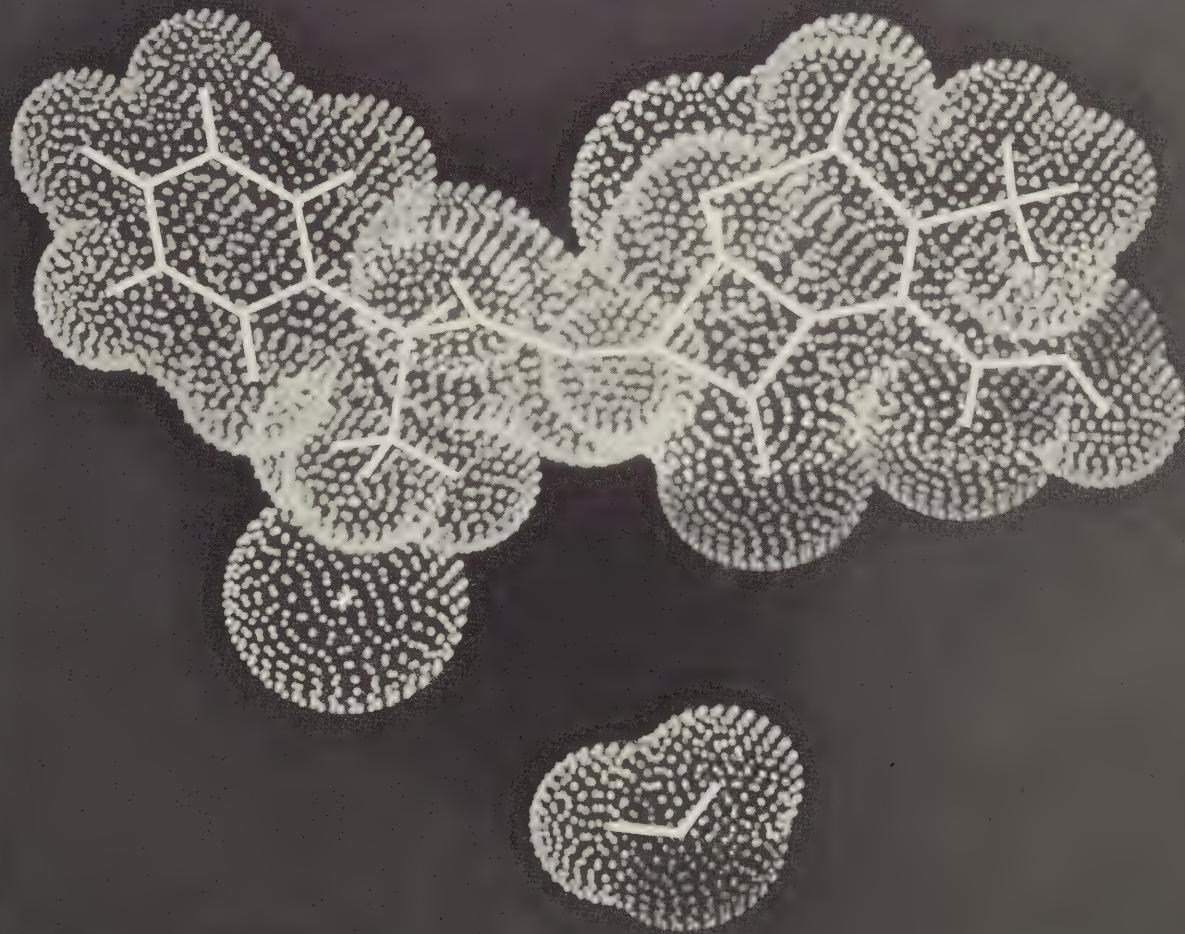
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ANNOUNCING

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Computer-generated molecular
structure of cephalixin
hydrochloride monohydrate

LETTERS



Dear David:

I have recently joined PCS as Manager of Professional Relations. My responsibilities include the role of liaison to the pharmacy community.

I am the person to contact whenever you or your members have a question or concern regarding PCS policy or related issues. I'll do my best to be responsive to your needs.

I'm looking forward to visiting with you in the future. Please do no hesitate to call me anytime I can be of service.

Sincerely,

Rick Walter, R.Ph.

PCS, Inc.
9060 East Via Linda
Scottsdale, AZ 85258
Telephone 602-391-4238

Dear Dave:

On behalf of the Maryland Board of Pharmacy, I have been asked to convey to you the provisions recently enacted in HB 1476 concerning the use of multi-prescription forms.

As provided by this legislation, a separate prescription form must be used for each controlled substance. The combination of controlled substances on the same blank with other non-controlled items is forbidden under provisions of this legislation. Although the pharmacist may transfer the other non-controlled prescriptions to separate forms, this presents an additional burden to the busy pharmacist.

The Board of Pharmacy would appreciate any notice to practitioners you could provide concerning separate prescriptions for CDS drugs. In addition, we would like to point out that prescriptions for a controlled dangerous substance may not be written on a pre-printed prescription form that states the name, quantity or strength of the controlled dangerous substance.

On behalf of the Board of Pharmacy, I would like to thank you in advance for your cooperation. If you have any questions concerning this, please feel free to contact me at any time.

Sincerely,
Paul Freiman
Board of Pharmacy

Editor's Note: The following letter was sent to the Maryland Insurance Commissioner to protest proposed changes by Blue Cross and Blue Shield units Over-65 Medicare Option coverage which would have made Mail Order Prescription Drugs available. The Commissioner turned down the BC/BS proposal.

The Honorable Edward J. Muhl
Insurance Commissioner
Department of Licensing and Regulation

Dear Commissioner Muhl:

On the behalf of the Maryland Pharmaceutical Association which is the state-wide professional society of pharmacists, I would like to provide additional written comments to those which were delivered at the hearing on Monday, November 23, 1987 regarding the proposal by Blue Cross and Blue Shield of Maryland to modify its Medicare Supplement program to include a mail order prescription drug option. While there were representatives of the Association present at the meeting and testimony was delivered, we felt it prudent to summarize a number of our arguments against the proposed changes as they relate to mail order prescription drugs for your review.

It is our belief, and that of a growing number of health care professionals in and out of pharmacy, that mail order prescription drug programs not only do not save money as purported, but actually represents considerable risk to the patient. There are statistical studies available which explodes the myth that mail order prescription drug plans actually save money. Recently the Federal Government, through the Office of Personnel Management, came to that very conclusion concerning Federal employees (article enclosed). This is especially true when one considers prescription drug waste due to large quantities that must be prescribed, changes in therapy, and the ultimate damage done when therapy is interrupted—an inevitable consequence of mail order drug therapy in the elderly population.

It is our firm conviction that every patient has the right to a *personal* consulting relationship with the pharmacist of that patient's choice. There is literally reams of data showing that patient compliance, especially in the elderly, is improved by the personal involvement of the pharmacist in patient consultation. So important is this element of contemporary pharmacy practice that the National Council for Patient Information and Education recently held a nationwide campaign to encourage patients to consult with their pharmacist about prescription drugs. October, 1987 was designated "Talk About Prescriptions" month with the slogan: "Before you Take it, Talk About it." The unfortunate miss-use of prescription drugs is considered such an important health hazard that it is referred to by NCPIE as the nation's "other drug problem." Patient

education is a growing and vital element of contemporary pharmacy practice which cannot be replaced by leaflets. This Association has just concluded a major public service campaign to encourage patients to take advantage of their right to this personal consulting relationship with their pharmacist (details enclosed). This Association and the Pharmacists of Maryland received a Governor's Proclamation for this effort. (Description enclosed). The removal of this important component of pharmacy services through the utilization of mail order plans is clearly a serious manner when considering modifying a major insurance program affecting thousands of Maryland's Seniors.

When prescription drugs are obtained from two different sources, as is necessary when a mail order patient must acquire acute prescription drugs from the local community pharmacy, no one is in position to perform the potentially life saving function of monitoring for adverse drug interactions. This is another vital part of pharmacy practice that every community based pharmacist performs daily. It is estimated that the average practicing pharmacist catches 1.2 potentially serious, and clinically significant drug interactions per day. These would go undetected in a split system.

Mail order drug schemes ask the elderly to keep track of two lists of drugs—one to be sent away for and one for drugs which can only be obtained in the community pharmacy. This is often a point of confusion with the elderly because of the different brands and names (generic, brand and chemical) that drugs have. In addition, the elderly are expected to remember each time to send their prescriptions away for refill in time to insure there is no break in their therapy. Again, this is often an unreasonable expectation which leads to gaps in therapy that can have serious consequences. How cost effective can a mail order prescription drug plan be if it results in hospitalization for elderly patients due to unintentional non-compliance with the physician's therapy?

What about the effect on the drug itself from exposure to mail service delivery? Admittedly there is little data on this subject, but we know that prescription drugs cannot be improved from exposure to the heat and cold and general treatment associated with this delivery.

What about control? In many cases these are potentially abusable substances being sent in an uncontrolled fashion. Who takes responsibility for the ultimate disposition of drugs that are dropped into the U.S. mail service? A return-receipt is not even required. In community pharmacy practice, the pharmacist has the assurance that the patient, or a responsible agent for the patient, has taken custody of the medication and understands the directions for use. Not so in mail order drug plans. Drug abuse is a major national problem and adequate control of the legitimate drug supply is an important element in its solution. Pharmacists routinely call prescribers when forged prescriptions are suspected. In

most cases, the pharmacist will verify a prescription for abusable substances whenever the patient or physician are unknown to that pharmacist. But, out-of-state mail order pharmacies cannot be expected to respond to this situation. In every case the identity of the patient and the prescriber will be unknown.

It has been our experience that, when given a choice, patients will opt for the personal involvement with a health care professional over the impersonal and erratic service of an out-of-state pharmacy. These pharmacies are not covered by the laws of Maryland governing the practice of Pharmacy designed to protect the public health of our citizens. These pharmacies do not even have a copy of the Maryland State Formulary for interchangeable drugs which is a list that can vary from state to state and is designed to guide Maryland pharmacists in drug product selection.

Patients resent the attempts to deny their right to freedom of choice by mandating a certain pharmacy outlet other than the personal relationship they have cultivated through years of patient-pharmacist interaction. Once the argument that mail order represents cost savings has been exploded, the inconvenience and real health risks associated with these plans cause most Seniors to return to their community pharmacy.

In dropping prescription drug coverage for all new Medicare Supplement subscribers except for the mail order option, Blue Cross and Blue Shield is not providing an option. The effect is the same as a mandate for the elderly patient worried about adequate health care coverage. They are forcing Seniors into a second, and we believe inferior, level of health care.

Prescription drugs are the most cost effective part of the health care delivery system available to the medical profession. But prescription drugs, especially many of the recently discovered and available products, can be extremely dangerous if miss-used. Pharmacists and physicians have developed a partnership of checks and balances over the centuries that involves the personal reinforcement of information, instructions and understanding to insure that the medical regimen works to the patient's benefit. Pharmacists, utilizing computers with patient profiles, screen for drug interactions, allergies, and over and under utilization. This entire system is circumvented when pharmacy services are fragmented by the use of mail order prescription drug programs.

We ask that you consider these arguments when addressing the proposed changes in the Blue Cross and Blue Shield Medicare Supplemental program. We believe that the consequences are serious. Please do not hesitate to contact me if you have any questions concerning our views or whenever I may be of some assistance to you.

Sincerely,

David A. Banta, C.A.E.
Executive Director

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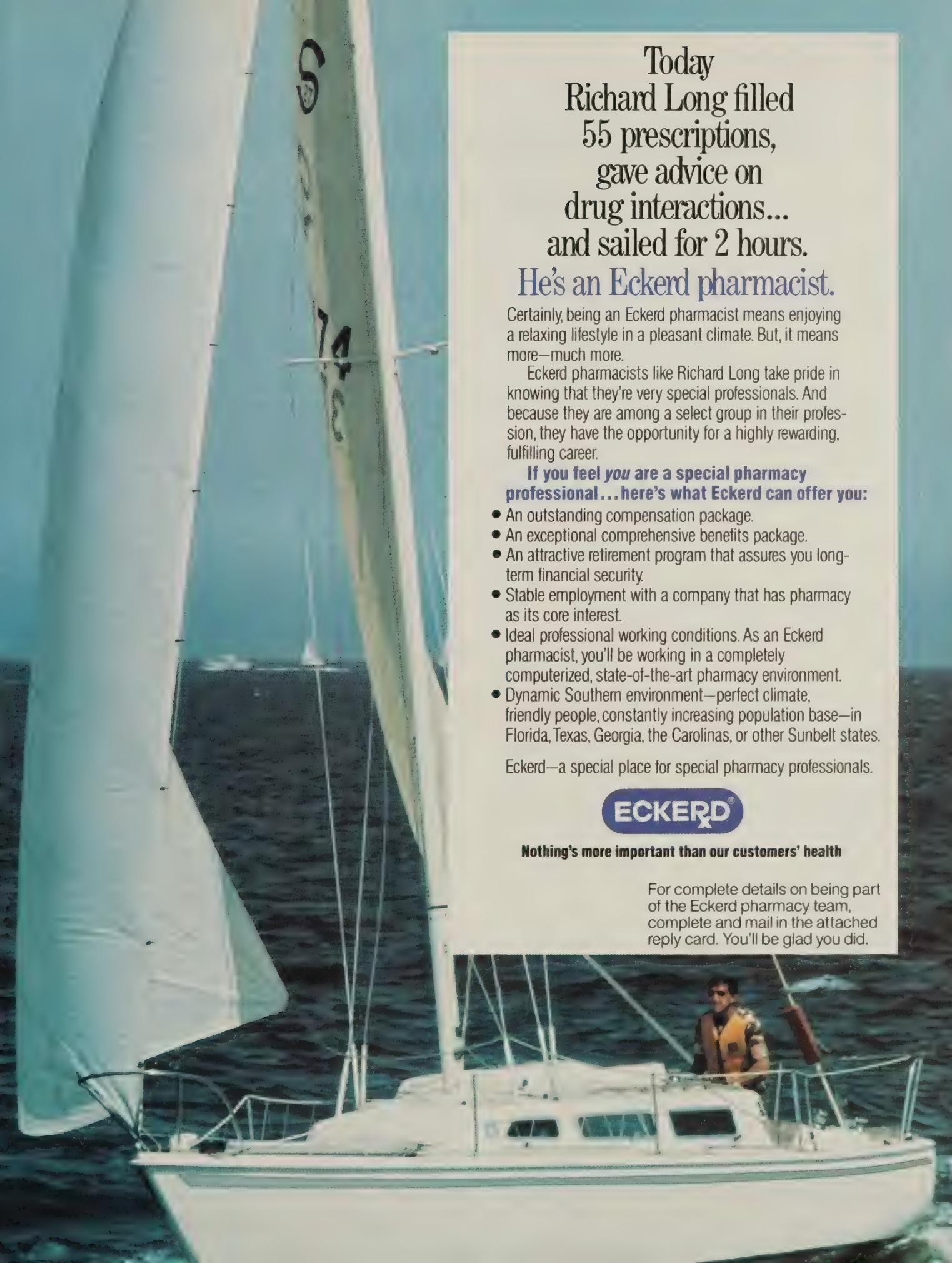
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Physician Dispensing and the Public Interest

by Jim Dickinson

Dispensing physicians. What happened? Just a few short years ago, everything seemed headed in the right direction.

Physician-pharmacist dialogs were improving, we felt the younger physicians had benefited from a certain integration of educational environments with pharmacy and other health professions students, pharmacists were no longer hopelessly subservient to "King Prescriber," and mutual respect was growing.

The patient was sure to be the ultimate winner.

Where did it all go? Many on both sides of the prescription pad are asking that question, and the asking stirs accusations—but very few answers.

Let's review some of them. Pharmacists in California started it by pressing for limited prescribing functions in the middle 70s. Physicians started it by putting pharmacy's professional aspirations down. Physicians should not have supported anti-substitution laws. Pharmacists should not have supported generics. Pharmacy schools should not have pumped too many new pharmacists into the market place. Medical schools should not have done the same with physicians. Florida pharmacists drive the last nail in the coffin by instigating the first prescribing law for pharmacists. Physicians drove the last nail in when they embraced dispensing for profit . . .

Who knows where it really began, and does it really matter?

Perhaps we should step back a few yards from this slugfest and try to see it from the ultimate referee's point of view—the patient.

Patients probably are not sufficiently sophisticated, or interested, now to cast a vote that means anything. But because they are the sole reason that we have physicians or pharmacists to begin with, you can be sure that they will eventually vote on these interprofessional squabbles.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

There's a strong probability that when they do vote, it will be in the form of a new law or two, at the state or possibly the federal level.

So what is in the best interests of the patient?

This should be the simplest of all questions, but when it is asked, all we can hear is a babble of self-interests.

Uninformed theorists and fanatics at the Federal Trade Commission, for instance, contend that uninformed consumers should be free to shop for their health needs from the widest possible range of choices, guided only by the din of unfettered free enterprise. This is the self-interest of political grandstanders speaking.

Semi-informed financial opportunists who used to be sell-anything entrepreneurs, now specializing in custom pharmaceutical kits for physicians, contend that uninformed consumers should place all of their reliance on the prescriber, foregoing pharmaceutical checks-and-balances. This is the self-interest of the quick-buck artist speaking.

Incompletely informed and professionally forgetful physicians, meeting as the American Medical Association in Atlanta in December voted to acknowledge mail-order prescriptions as a safe and established alternative distribution system. They do this citing security studies done in the 1970s, when there were no for-profit mail-order pharmacies. This is the self-interest of vengeful combatants, stung by critics of their "right" to dispense, speaking.

So what is the patient's interest?

It's sad that in this cacophony of self-interests we should have to ask, and that there will be disagreements based on self-interest when answers are given.

Try this definition of the patient's interest:

The patient is entitled to conscientious, competent "hands-on" care by health professionals with the fullest personal training and experience in the care being given.

Notice that money is not mentioned. That is because the care comes first, and the money second.

Notice that convenience is not mentioned, either. That, too, is because the care comes first, and the convenience second.

It may well be that the interprofessional bitterness we're hearing comes from too many actors participating in the patient's ignorance, from too many people profiting from patients not yet knowing what they're missing.

But that can't go on forever. Patients will find out. And when they do, the warring health professions may find out that patients are ignorant about something else—the supposed value of professional turf.

They won't care who is the boss, who is subservient to whom, or what professional dignities were affronted when one party did something the other didn't like.

All the patient is interested in is knowing that the care they got was the best available. Often, that is as

much a perception as a reality. It used to be called "bedside manner."

Aging Americans, who buy the most health care, remember those days. A powerful and growing majority, if they perceive themselves to be getting less care than they need from the health care system, they will force the issue with blunt instruments like lawsuits and legislation.

Against dispensing physicians, one such blunt instrument is the Wyden bill, H.R. 2168, which has now drawn the endorsement of the National Council of Senior Citizens because of the clear conflict of interest that dispensing physicians have.

Seniors can already see that pharmacists should stick to traditional pharmacy, and physicians to traditional medicine. Others will catch on, too.

It's the patient who's boss.

Taxes: Points to Consider for Your Pharmacy

James R. Talley, M.S.

School of Pharmacy

Northeast Louisiana University

Monroe, Louisiana

Auto Expenses

The number of rules and limitations for deducting automobile expenses may appear confusing and complicated with tax reform. However, the basic rules still apply and you have two options for deducting automobile expenses:

Option 1—Actual Expenses: You may deduct the actual expenses incurred to operate and maintain an automobile for your pharmacy. Actual expenses include items such as depreciation, taxes, repairs, gasoline, oil, insurance, licenses, and possible interest. However, if you use the automobile for both business and personal purposes, then expenses must be apportioned for business (deductible) and personal (non-deductible).

Option 2—Standard Mileage: You may deduct a standard rate of 21 cents per mile for the first 15,000 miles and then 11 cents per mile over 15,000 miles of business travel for the year. The 11 cents per mile also applies when the automobile has been fully depreciated or used for 60,000 business miles.

Depreciation Rules: New depreciation rules apply for the purchase of a business automobile. The new de-

preciation rules have reduced the benefit of deducting actual automobile expenses as a result of reducing the depreciation amount available each year (Table 1). Several additional tax considerations for an automobile utilized in business are:

- depreciated over five instead of three years,
- no investment tax credit,
- Mid-quarter convention may limit depreciation for the year placed in service,
- luxury automobiles (costing more than \$12,763) are subject to maximum depreciation limits (Table 1),
- sales taxes added to the depreciable basis rather than deducted,
- straight-line depreciation must be applied if the automobile is used 50% or less for business.

Avoid Estimated-Tax Penalties

As a pharmacy owner, you may be paying an estimated tax on your nonsalary income. With tax reform,

TABLE 1
**Depreciation Limits for Automobiles Placed in Service
 After 12/31/86**

| Year | Depreciation Percent | Luxury Car Maximum Depreciation Limits |
|------|----------------------|--|
| 1 | 20.00% | \$2,560 |
| 2 | 32.00% | \$4,000 |
| 3 | 19.20% | \$2,450 |
| 4 | 11.52% | \$1,475 |
| 5 | 11.52% | \$1,475 |
| 6 | 5.76% | \$1,475 |

taxes withheld from your salary plus your estimated-tax payment must now equal 90% of your total tax due. If you have underestimated your tax and are subject to a nondeductible penalty on the underpayment, then increase your salary withholding to compensate for the shortfall before the end of the year. The Internal Revenue Service will prorate the total amount withheld over the entire year. Thus, one-fourth of the amount withheld will be credited with each quarter of your estimated tax liability. However, if you added the shortfall of your last quarter's estimated tax payment, then you would be subject to penalties for the first three quarters.

Year-End Bonus

As a pharmacy owner, you may be planning to provide yourself with a bonus at the end of the year. The actual amount of your bonus probably involves waiting until near the end of the year before you can estimate your profit picture. Beware, because the IRS may view this practice as representing a nondeductible dividend rather than compensation. This problem can be avoided by early in the year documenting in your business minutes the amount of your bonus and services rendered to obtain the bonus. It may be desirable to establish a large bonus and correspondingly reducing your salary. Then adjust your actual bonus at the end of the year. However, if your pharmacy is an S corporation this approach may not be applicable because all profits are taxable to you.

Charitable Contributions

There exists a quirk in the tax laws that may be of benefit to your pharmacy and your favorite charity. However, because the process is complicated you should discuss this approach with your tax adviser before proceeding. The new tax laws have eliminated the special tax rate on long-term capital gains. It is possible to deduct the fair market value of any property contributed to charity, if the property would have produced a long-term capital gain if sold. If the value of the stock in your pharmacy has increased in value, then one way to take advantage of this tax quirk is to donate shares of your pharmacy to your favorite charity and arrange to buy it back at full value. The charity gets the money, you get the gift deduction, you have cashed out money from your pharmacy dividend free, and in the end you still retain 100% ownership of the corporation's stock.

Beware, because if the charity is obligated to sell the stock back to your company, then you lose the deduction. However, you can prohibit sales to anyone else. The charity will probably be more than willing to sell the stock back to your company at full value because stock in a privately held company would be of little use to the charity. As a final point, the IRS will require an independent appraisal if the stock is worth more than \$5,000.

Taxes in 1988

Tax rates move down in 1988. In addition, long-term capital gains will be taxed the same as ordinary income in 1988. Table 2 contains a summary of personal tax rates for 1987 and 1988. Now is the time to start developing your tax strategy. You are advised to consult your tax attorney or CPA for specific details.

TABLE 2
Taxable Income: Personal Tax Rates

| Tax Rate | Joint Returns | Single Individuals |
|----------|----------------|--------------------|
| 1987 | | |
| 11.0% | Up to \$3,000 | Up to \$1,800 |
| 15.0% | 3,000–28,000 | 1,800–16,800 |
| 28.0% | 28,000–45,000 | 16,800–27,000 |
| 35.0% | 45,000–90,000 | 27,000–54,000 |
| 38.5% | >90,000 | >54,000 |
| 1988 | | |
| 15.0% | Up to \$29,750 | Up to \$17,850 |
| 28.0% | 29,750–71,900 | 17,850–43,150 |
| 33.0% | 71,900–149,250 | 43,150–89,560 |
| 28.0% | >149,250 | >89,560 |

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MVCP SERVICES MID-ATLANTIC REGION



After ten years of service as MPhA Executive Director, David Banta recently announced his resignation to become Deputy Executive Vice President of the American College of Health Care Administrators. A Search Committee has been formed to seek his replacement.



Steven Cohen has been voted by the other Commissioners of the Maryland Board of Pharmacy to serve as President. He is currently Chief of Material Management at Good Samaritan Hospital.

From the M.Ph.A. Legislative Committee: Heres what you can do to help



REGISTRATION AND VOTING

1. Register to vote and encourage family and friends to register also.
2. Check out absentee registration rules with your local registrar if you are out of town frequently.
3. Vote in primary and general elections and encourage family and friends to vote also.
4. Vote by absentee ballot if you are going to be out of town.

PARTY AND CAMPAIGN ORGANIZATION

1. Get active in a political party of your choice.
2. Serve on a political party committee.
3. Work on a candidate's campaign committee.
4. Volunteer to:
 - a. help a candidate or party address and stuff envelopes
 - b. distribute campaign literature in your neighborhood
 - c. prepare voter index cards and lists for campaigns
 - d. work in a phone bank to recruit other party workers or get people out to vote on Election Day
 - e. organize rallies and fund-raising events
 - f. type letters
 - g. act as a poll watcher
 - h. host a coffee/tea party for a candidate
 - i. design campaign posters and ads
 - j. give rides to the polls
 - k. be a precinct worker or a block captain
 - l. write campaign material
 - m. babysit for voters with small children on Election Day
 - n. decorate meeting halls
 - p. help publicize campaign and party events through the media

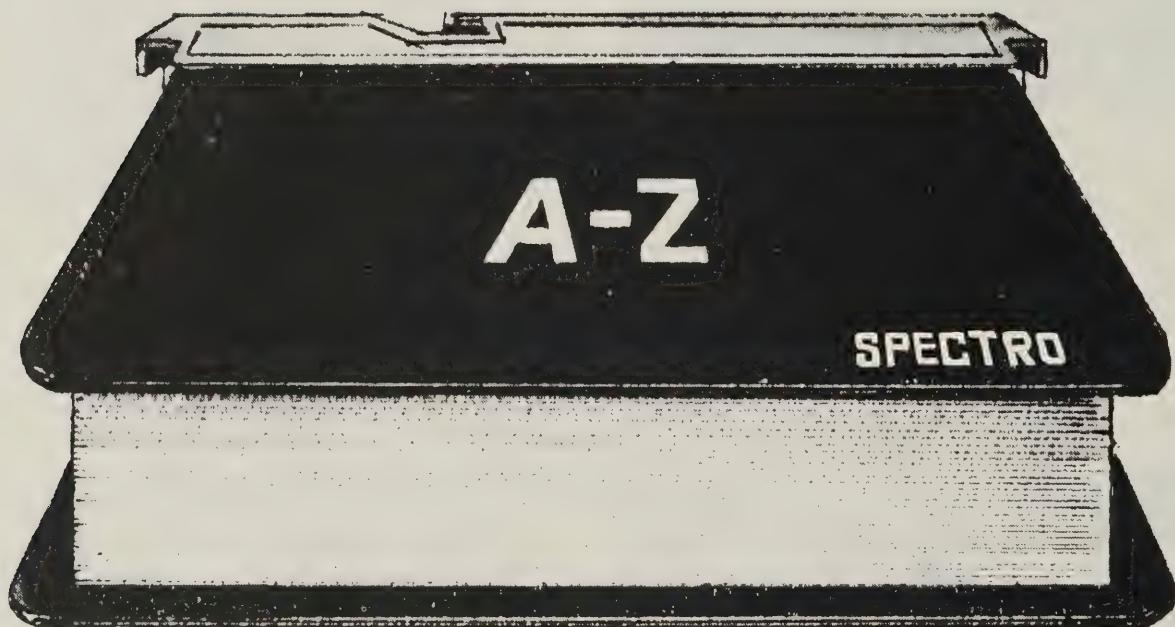
FUNDRAISING

1. Contribute financially to a political party or candidate and solicit funds from others.
2. Volunteer your services to provide expertise in election laws, accounting, fund-raising, marketing and promotion.

SUBSTANTIVE ACTIVITIES

1. Keep informed on vital issues facing the community and government.
2. Know the candidates and their qualifications.
3. Attend meetings of the city council, school board, or other public boards.
4. Communicate on issues with your elected representatives — local, state and national.
5. Write letters to the editor stating your position on a particular issue.
6. Hold appointive or elective office in government.

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calendar

- Feb. 7 (Sun) MPhA MID YEAR MEETING—AN-NAPOLIS HILTON
Feb. 14 (Sun) Eastern Shore Association Dinner—Federalsburg
Feb. 17 (Wed) AZO Evening Seminar
April 19 Baltimore VA 5th Annual Conference, School of Pharmacy
Mar. 13 (Sun) BMPA Annual Dinner Dance—Bluefield
Mar. 20 (Tue) AZO Breakfast Seminar

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

Maryland Society of Hospital Pharmacists Meetings

MARK YOUR CALENDARS, PLEASE:

The 1987-1988 MSHP Roster of Monthly Programs is under development. Please note the following dates and sites on your calendars:

FEBRUARY 11, 1988 —TBA (To Be Announced)
MARCH 10, 1988 —TBA (To Be Announced)
APRIL 14, 1988 Mercy Hospital
MAY 12, 1988 Johns Hopkins Hospital

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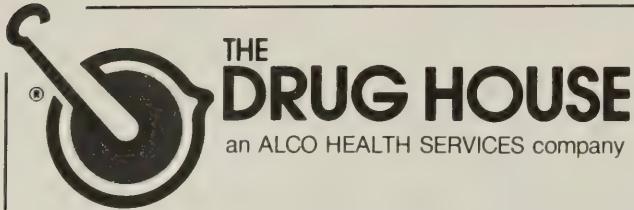
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4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
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6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?



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PRESIDENT'S MESSAGE

This year, the American Pharmaceutical Association has selected Peter P. Lamy, Ph.D. as the 1988 recipient of the Remington Honor Medal, pharmacy's highest honor.

Dr. Lamy is internationally known for his foresight and efforts in educating health professionals, government agencies and consumers about the importance of geriatric pharmacy. We in Maryland have benefited greatly from his knowledge and research, his help to pharmacy students, and his devotion to the Maryland Pharmacists Association.

His contributions to pharmacy touches all practice sites—community, hospital, institutional, home care, and many more. We congratulate him on this new honor.

Peter Lamy is truly Maryland Pharmacy's Renaissance Man.

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Correspondence Course Advising Diabetic Patients on Glucose Testing Products

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Goals

The goals of this lesson are to:

1. discuss the proper technique for testing urine or blood for glucose with home testing products; and
2. explain the rationale for use, advantages and disadvantages, and special precautions of glucose testing products.

Objectives

At the conclusion of this lesson, participants will be able to:

1. identify the mechanism of action of urine and blood tests for glucose;
2. pick from a list of drugs and chemicals, those reported to interfere with glucose urinalysis results;
3. select the advantages and disadvantages of using urine and of using blood to measure glucose; and
4. list advantages and precautions to observe when using electronic meters to measure blood glucose.

Glucose Testing Products

Diabetes mellitus reportedly affects 15 million Americans. It is the third leading cause of medically-related death in the U.S., and the most prevalent cause of blindness in Americans under age 65. Diabetes directly or indirectly leads to long-term complications such as diseases of the nervous system (neuropathy) and kidney (nephropathy).

There is no cure for diabetes. Following diagnosis, however, insulin-dependent diabetes can largely be controlled at home by determining proper insulin dosage using OTC urine and blood testing products for glucose.

While the exact relationship between blood glucose values and development of long-term complications of diabetes is unknown, most experts agree that a direct correlation exists. Animal studies indicate that if blood glucose values are maintained near normal, many of the devastating complications can be minimized. Data from most human clinical trials support this observation.

This lesson discusses diabetic testing products for glucose. It describes those that use urine, and others that use blood as the testing

medium. It compares products and tells how to properly collect and use a urine or blood sample. It also stresses patient advice.

Urine Testing

Urine is a useful testing medium because it contains the excretory products of reactions occurring within the body. It, therefore, reflects the body's metabolic activities. Urinalysis provides information relating to health, and it serves as a valuable resource for testing for numerous disease processes, including diabetes mellitus.

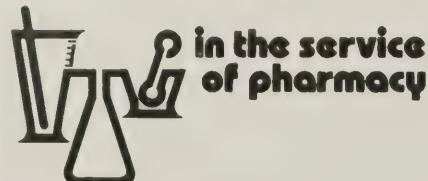
Today, more emphasis is placed on testing of blood rather than urine for glucose concentration. Although urine testing has some disadvantages (Table 1), routine urinalysis is still useful for diagnosing and monitoring physiological parameters such as the presence of glucose in the urine. Urinalysis testing is valuable because it can be readily, safely, and inexpensively performed at home.

Urine Contents. Before discussing procedures for testing glucose in urine, it will help to quickly review what normal urine contains. Although the principle constituent is water, urine also contains many other chemicals as well. Table 2 lists important constituents of urine.

TABLE 1

Disadvantages of Urine Glucose Testing

- Does not indicate minute-by-minute changes in blood glucose levels
- Does not correlate between urine and blood glucose levels
- Does not detect hypoglycemia
- May show variable results depending on person's renal glucose threshold limit
- Is susceptible to numerous potential drug interactions
- Is distasteful to some persons



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TABLE 2

| Major Constituents of Normal Urine and Concentrations | |
|---|------------------|
| Chloride | 200 mEq/L |
| Creatinine | 150 mg/dL |
| Glucose | 10 mg/dL |
| Lead | 10 mg/dL |
| Phosphorus | 100 mg/dL |
| Potassium | 80 mEq/L |
| Protein | 8 mg/100 ml dL |
| Urea | 3 gm/100 ml dL |
| Uric acid | 80 mg/100 ml dL |
| Volume: | 1000-1500 ml/day |
| Sp Gr: | 1.002-1.030 |
| Total Solids: | 50-70 g/day |
| pH: | 5-8 |

Urine constituents reflect the amount of electrolytes and proteins ingested in the diet. As can be seen from Table 2, normal urine does not contain significant glucose. There is a minute amount (i.e., 2 to 20 mg/ml), but urine glucose testing products are not calibrated to detect this.

Glucose cannot be present in urine in significant quantity because it is such a large molecule and does not easily move across biological membranes. Moreover, the body has a normal mechanism (which involves insulin) to conserve glucose for use in producing nutrition and energy. When this system malfunctions, as in diabetes, hyperglycemia and glucosuria occur. More glucose will pass out with the urine. Detecting and measuring it forms the basis for diabetic urinalysis tests.

Urine Collection Techniques. Proper collection of urine is one of the most important aspects of urinalysis. Every effort should be made to assure that the diabetic patient understands the correct procedures and follows them. Specimens that are carelessly collected or stored cannot be expected to give a high degree of reliability.

There are several types of urine samples used for testing urine glucose. The most common types follow.

Fasting specimen: the second sample of urine that is collected at least 4 hours after the previous meal.

First morning specimen: the first specimen voided upon arising in the morning.

Moisten in urine stream: the product is held in the urine stream after some urine has been voided.

Copper Reduction Test

Historically, **Benedict's Solution** was the earliest reliable test for urine glucose. While development of this reagent was a major stride forward in its day, it has since fallen by the wayside because of its cost, and the inconvenience of needing to heat the urine sample.

Clinitest tablets have replaced Benedict's Solution because of increased sensitivity and convenience. Each tablet contains cupric sulfate, sodium hydroxide, sodium carbonate, and citric acid. To perform the test, a urine sample is placed in the test tube supplied with the product. Water is added, and a Clinitest tablet is dropped into the tube. The color changes that occur are carefully observed.

The reaction between ingredients in the product and glucose create heat and bubbling. Fifteen seconds after bubbling ceases, the tube is shaken gently to distribute the color. The color in the tube is compared to the color blocks on the package label. Any shade of blue indicates a negative response; color hues of green through brown to orange indicate a positive reading.

Diabetics must continually observe the solution to avoid the **pass-through-phenomenon**. This occurs when glucose concentrations are greater than 2 percent. For example, a glucose concentration of 5 percent which normally shows as an orange color, may quickly fade back to brown. If the observer notices only the end color (brown) without having first noticed the orange shade, the glucose concentration may be misinterpreted.

To avoid this pass-through-phenomenon, the "2-drop" method of utilizing Clinitest tablets was developed. In this procedure, 2 drops of urine, rather than 5, are mixed with 10 drops of water. A special color chart for use with this test quantitates glucose values up to 5 percent.

While rare, diabetics may have urine glucose concentrations above 5 percent. For these individuals, a pass-through color change from orange to brown may be seen even with the 2-drop method. To detect these larger concentrations, 1 drop of urine is added to 11 drops of water. The 2-drop chart is used to compare the final color in the test tube. The

result is multiplied by two to give the correct glucose percentage. Urine glucose concentrations as high as 10 percent can be detected using this method. Patients with levels this high are candidates for blood glucose testing, rather than urinalysis.

Diabetic patients should be reminded to keep bottles of Clinitest tablets tightly closed. The sodium hydroxide is anhydrous and may absorb moisture. Cotton may also react with the tablets and must not be placed in the bottle. The bottle should not be stored in a refrigerator since this increases the chance of collecting moisture. The tablets should also be kept out of light, away from heat.

Clinitest tablets are normally speckled with light blue particles. If they become discolored with darker spots, they will not give reliable results and should be discarded. Individuals using Clinitest only infrequently, or in hot humid climates, should purchase foil-wrapped tablets. Clinitest tablets are extremely toxic if ingested, and should be kept out of the reach of children.

Only test tubes supplied by the manufacturer should be used. When different sized tubes are used, the rate of heat loss may change, and possibly render the results inaccurate.

The major advantage of Clinitest over a glucose oxidase product is that it is more quantitative. The primary drawback is that it measures total reducing substances in the urine (Table 3). A false-positive response may, therefore, be observed.

Diabetics taking any of the drugs listed in Table 3 should be advised that they may interfere with Clinitest results. For those patients, switching to a glucose oxidase product should solve the problem.

Glucose Oxidase Tests

These products (Table 4) contain the enzymes, glucose oxidase and peroxidase. Glucose oxidase reacts with urinary glucose specifically to form gluconic acid and hydrogen peroxide. Hydrogen peroxide, in turn, reacts with the second enzyme, peroxidase, to release oxygen which changes the color of a dye (chromogen). The intensity of color change is dependent on the amount of oxygen produced, and is measured against a

TABLE 3

| Substances Reported To Interfere with Clinitest Urine Testing |
|---|
| Aminosalicylic acid |
| Ascorbic acid |
| Catecholamines |
| Cephalosporins |
| Chloral hydrate |
| Chloramphenicol |
| Ethacrynic acid |
| EDTA |
| Hydrogen peroxide |
| Indomethacin |
| Isoniazid |
| Levodopa |
| Metaproterenol |
| Methyldopa |
| Methenamine salts |
| Morphine |
| Nalidixic acid |
| Niacin |
| Nitrofurantoin |
| Penicillins |
| Phenols |
| Phenothiazines |
| Probenecid |
| Salicylates |
| Sulfonamides |
| Tetracyclines |
| Thiazides |

color chart printed on the package label.

Since different products use various chromogens, colors obtained with the various products may differ. To illustrate, Clinitest shows a blue/purple color for positive tests. TesTape displays various shades of green. Diastix shows shades of green and brown for positive reactions. Chemstrip uG shows a darkening color from yellow through various shades of green. Its manufacturer states that the color scale is lot specific for each batch.

To properly use these products, the test strip is placed in a urine sample and quickly removed. It should then be tapped against the side of the container to remove excess urine. At the indicated time, the color on the reagent pad is compared to the color blocks on the container's label.

Special care should be exercised to avoid contaminating the test area of the reagent strip. Perspiration, tears and other contaminants can alter test results.

Urine samples should be freshly collected; for most products, urine should not be more than 1 hour old. TesTape may not be used on urine samples more than 4 hours old. If the

urine has been refrigerated, it must be brought to room temperature before the test is conducted.

The products weaken over time. If Diastix becomes inactivated, a green discoloration of an area that is supposed to be blue occurs. A brown discoloration of the reagent strip is a telltale sign that it has decomposed. The manufacturer of TesTape suggests that any unused portion be discarded if the package has been opened for 4 months or more. Other products may deteriorate and should be replaced regularly as well. All products should be stored in a cool, dry place, but not in a refrigerator.

There are substances which interfere with glucose oxidase testing methods (Table 5). Unlike the copper reduction tests, most of these interfering substances cause a false-negative, rather than a false-positive, response. This occurs because there are more interfering chemicals that prevent the enzymatic reactions of the strip, rather than enhancing it.

TABLE 4
Glucose Oxidase Urinalysis Testing Products

| Product | Manufacturer |
|--------------|-------------------|
| Chemstrip bG | Bio-Dynamics |
| Clinistix | Ames |
| Diastix | Ames |
| Kyotest uG | Kyoto Diagnostics |
| TesTape | Lilly |

TABLE 5
Substances Reported to Interfere With Glucose Oxidase Urine Tests

| False Positive |
|---------------------|
| Chlorides |
| Hypochlorites |
| Hydrogen peroxide |
| Peroxides |
| False Negative |
| Ascorbic acid |
| Aspirin |
| Bilirubin |
| Catecholamines |
| Cysteine |
| Epinephrine |
| Ferrous sulfate |
| 5-Hydroxytryptophan |
| Levodopa |
| Methyldopa |
| Sodium bisulfite |
| Sodium fluoride |
| Tetracyclines |
| Uric acid |

Testing the Blood for Glucose

Although diabetic patients have relied on urine testing to monitor glucose levels present in the blood for over four decades, more recently products have become available for directly measuring glucose levels using blood samples. These tests are more sophisticated than urine tests, and are an extension of the testing procedures usually performed by physicians. Self-monitoring of blood is steadily gaining in general popularity and acceptance.

Home blood-testing products (Table 6) provide quantitative readings of glucose concentrations. There are also various collection aids to assist diabetics in painlessly obtaining blood samples.

The advantage of testing for glucose in blood samples rather than urine are well-documented (Table 7). Blood testing has improved overall control of insulin-dependent diabetics. It has also brought about better control of pregnant diabetics with resultant decreased fetal morbidity.

The majority of diabetic patients in one survey would rather prick their fingers for blood than obtain a urine sample. They have developed greater motivation for monitoring their disease and controlling it with blood testing. Knowing how and when their glucose concentration fluctuates in response to various foods and exercise helps diabetics comply with their therapeutic regimens. Blood testing results in improved diabetic control when individuals couple the results of monitoring with adherence to the other components of diabetic management such as diet, exercise, and multiple insulin injections.

A major advantage of blood glucose tests is that urinalysis cannot be totally relied on to monitor diabetic control. Diabetics experience trouble distinguishing between hypoglycemia and a feeling of fatigue. When such symptoms appear, patients don't know whether to take glucose or get some rest. Blood glucose monitoring will immediately indicate impending hypoglycemia. Rapid adjustment of insulin dosage or ingestion of a carbohydrate snack can then be undertaken. Blood monitoring also avoids the need for ingesting unnecessary snacks when hypoglycemia is suspected but blood glucose is

TABLE 6

| Reflectance Meters and Blood Glucose Test Strips | | | |
|--|----------------|--------|-----------------------------|
| Device | Manufacturer | Range | Compatible Strip |
| Accu-Chek II | Bio-Dynamics | 20-500 | Chemstrip bG |
| BetaScan (B) | Orange Medical | 0-400 | TrendStrip |
| Diagem | Seton | 18-360 | Chemstrip bG |
| Diascan | Home Diag | 10-600 | Diascan |
| Diatron | Dextrotron | 9-450 | Chemstrip bG/ Dextrostix |
| Glucochek SC | Larken | 10-400 | Chemstrip bG |
| Glucometer II | Ames | 40-400 | Glucostix |
| Glucoscan | LifeScan | 25-450 | Glucoscan |
| TrendsMeter | Orange Medical | 0-396 | TrendStrip |

normal.

Blood glucose monitoring is reported to improve the patient's overall outlook. The patients express increased self-confidence when they are at least partially in control of their condition, rather than at the mercy of processes (i.e., urine testing procedures) that they don't understand.

Drawing Blood and Using the Blood Testing Products

To test blood for glucose content, a large drop must be drawn. The earlobe, heel of the foot, and finger are good sources; most diabetics prefer the latter. If the area is clean, it is not necessary to first swab it with alcohol. If alcohol is used, it must be allowed to evaporate completely before puncturing the skin.

The best area to prick is the side of the finger, because it is easier to penetrate. Also, there is a good blood supply and few nerve endings there, so pain is minimal. Some people rotate finger sites; others continue to use the same general area until a callus forms. The area can first be warmed to facilitate drawing blood. After pricking with a lancet, the area is then "milked" to squeeze blood from it.

Lancets can be reused by the same person. Following each use, they should be wiped clean with alcohol, and stored in their protective cover. After several punctures, they become dull, cause increased pain, and should be discarded.

The blood sample should be smeared across the entire chemically-treated test pad. Depending on the particular product, after the proper time interval, the strip is dabbed dry (dry-wipe) or rinsed with water (wet-wash) and

then dabbed dry. Again, depending on the product, the strip is read immediately, or after several seconds. This can be achieved by visually comparing the color of the strip to the color sample blocks that come with the testing kit.

Strips may also be read in a meter. The electronic meters provide the same basic information, but are calibrated differently. They are also designed for use with specific test strips. Unless the labeling of the meter or strip indicates that the products are compatible, they should not be used together. To keep the meter working as accurately as possible, the opening on the meter where the strip is placed must be kept clean.

Diabetics must be motivated to perform the test properly. They must understand the program objectives and comply with all aspects of testing. A diabetic's control, which is achieved with blood or urine testing, may deteriorate over time because his motivation decreases. Pharmacists can help improve this by showing interest in the patient's needs

and checking with him from time to time to see how he is doing.

An individual's performance and budget often determine whether he will use the strips alone or with a meter. Many will be satisfied with visually reading them. Others will prefer the meters because they feel they are more accurate, or because they have vision impairment or trouble distinguishing colors. Some state that they prefer a meter because it is more fun to use than measuring a color change against a printed color block.

Summary

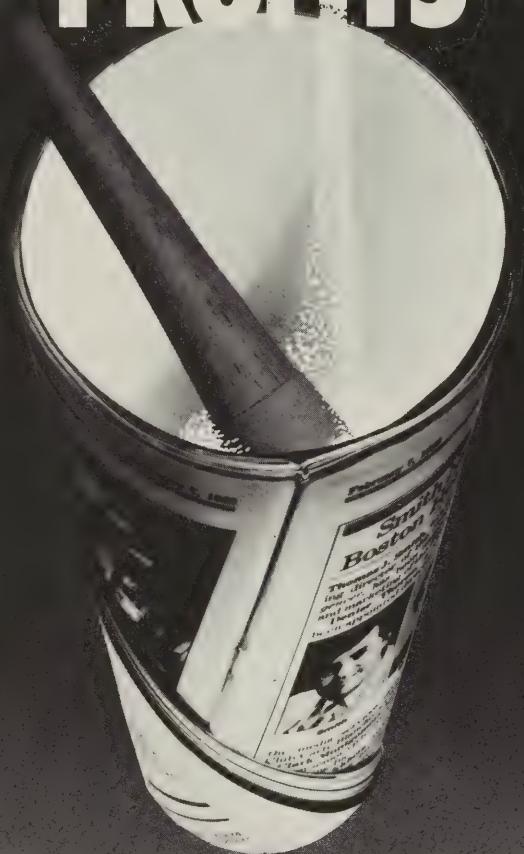
Monitoring blood glucose levels at home using blood or urine as the testing medium is accepted by most diabetic patients. There are numerous reasons that favor a regular program of home monitoring. Glucose concentrations can be accurately measured during various daily activities. In fact, adjustment of insulin dosage and meals to facilitate participation in active sports can be accomplished safely.

Insulin doses and meal-planning programs can be immediately integrated and adjusted to achieve improved glycemic regulation. The frequency of overdosing with insulin, and resulting rebound hyperglycemia following hypoglycemia, should be reduced. Additionally, home monitoring of glucose levels may help prevent long-term diabetic complications.

TABLE 7

| Advantages of Testing the Blood for Glucose Versus the Urine |
|---|
| <ul style="list-style-type: none"> ● Tests are more accurate; results are quantitative instead of semiquantitative ● Detects blood glucose concentrations at levels below renal threshold values ● Hypoglycemic reactions are confirmed ● Provides knowledge of blood glucose fluctuations in response to normal daily activities ● Avoids problems of handling urine, which some patients dislike; does not require the same amount of privacy as urine tests ● Less time needed to obtain compared to a double-voided urine sample ● Increases patient's knowledge about his disease and compliance with treatment ● Allows physician to alter treatment type/frequency without hospitalizing the patient |

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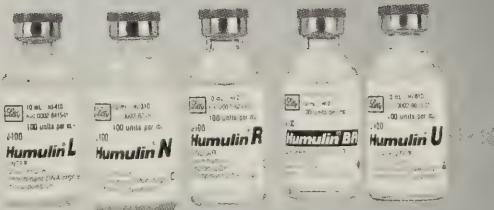
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Drug Use and The Elderly: Some Observations and Recommendations

by Peter P. Lamy, PhD

The Elderly

There are approximately 22 million persons between the ages of 55 and 64 years and 27 million 65 years old and over. Those 49 million people account for 21% of the American population. Those 60 and over account for 17%, and those 65 and over account for 12%. It is important to realize that the aging population itself is aging, those 85 years old and over constituting the fastest-growing segment of the US population.

The Health Status of the Elderly

At least 80% of those 65 years old and over suffer from one chronic disease and of those, as many as 40% may suffer from two or more chronic diseases. In one recent study (Anderson RJ, Excerpta Medica 5:26, 1982) of 102 elderly hypertensive patients, it has been shown that almost 40% also suffered from degenerative joint disease (osteoarthritis), some 25 to 30% suffered from diabetes mellitus, 20% from congestive heart failure, angina, or cerebrovascular disease. Thus, multiple pathology in about 30 to 40% of the elderly is the rule, rather than the exception. Most often, elderly suffer from hypertension. As many as 40 to 60% of elderly are thought to suffer from this problem, which is a risk factor for cardiovascular, cardiac and cerebrovascular problems and ought to be treated. Hypertension occurs more often in females than in males. The health, social and economic problems of the elderly, particularly those 70 years old and over, are those of females. Females, among the very old outnumber males by a ratio of 3:1.

Those over 65 represented 25% of all physician visits in the US in 1986. Almost 162 million visits were by females and 105 million by males, the rest being unspecified.

The aging of the population 65 years old and over has many implications. For example, among those 65 to 74 years old who may be hospitalized, only 4% are referred to long term care upon discharge from the acute care hospital. However, among those 85 years old and over, almost 25% are referred to long term care.

The aging of the older population has other implications to health care. Chronic disabilities occur in 15% of the total US population, but in 66% of those 85 years old and older.

Where are the Elderly?

Only about 5% of the elderly, or 1.4 million, are cared for in nursing homes. However, for every elderly nursing home resident there are already four adults living in the community of similar age afflicted with equally serious medical problems. Most at risk are those living alone. In 1987, 8.8 million elderly live alone (those living alone make more medication errors). Sixty-seven percent of those are elderly widows and 14% other elderly females. Thus, females account for 81% of those living alone.

Elderly living in the community may be divided into one of four major categories:

1. Independent
2. Independence threatened
3. Independence delegated
4. Dependent

An elderly woman with osteoarthritis and/or asymptomatic coronary artery disease may be medically stable. However, she may lose "independent" status when coronary artery disease progresses or if osteoarthritis gets worse. She may then be unable to pursue activities of daily living, such as shopping, threatening her independence. Worsening of a disease process may occur more rapidly when medications which are needed are not available.

When independence is delegated, family caregivers often become responsible for the community-living patient. On the average, the caregiver's age is slightly more than 60 years of age and many, indeed, are as old as the patient being cared for. Often, "caregiving" involves 124 hrs/week. Caregivers, therefore, are often exhausted and depressed, needing themselves multiple medications.

DRUG USE FOR AND BY THE ELDERLY

An Overview

Only prescription drugs will be discussed, although 40% of all drugs used in nursing homes are non-prescription drugs and 66% of community-living elderly use non-prescription products.

The date base is poor. Often, data are based on manufacturers' sales, or sales by wholesalers, or on prescriptions dispensed. Actual use data are scarce.

It is known that elderly often lack financial resources needed to purchase prescription drugs. Some studies have indicated that as many as 36% of the elderly may, at times, have problems purchasing their drugs.

It is also known that 40% of elderly patients will stop taking a chronic care drug within the first year of its use. Nevertheless, is it generally agreed that the elderly (12% of the population) receive about 32% of all prescription drugs, and that 70% of all drugs prescribed for the elderly are chronic care drugs. In 1986, new drug therapy accounted for almost 91 million prescriptions for those over 65, but there were 254 million refill prescriptions (in contrast, new prescriptions outranked refill prescriptions for those under 65). Yet, questions remain.

In one study (Br Med J 294:289, 1987), under-reporting of medications was common and increased as the number of prescribed drugs increased. In general, it is felt that there is still a significant incidence of inappropriate prescribing for the elderly (JR Coll Phys 21:39, 1987). It is generally believed that community-living elderly use about three prescription drugs/day and possibly two non-prescription drugs.

Variability of Drug Use

Drug use varies significantly with the site of care and with the age of the patient. Drug use is probably highest in nursing homes. About 45% of patients over 65 in US nursing homes are on five or more prescription drugs a day (Table I):

TABLE I
Prescription Drug Use

| No of Rx Products | Age/Location of Patient | | |
|-------------------|-------------------------|----------------|---------|
| | 65+/NH (%) | 65+ non-NH (%) | 65- (%) |
| One | 12.0 | 27.4 | 43.9 |
| Two | 14.0 | 21.5 | 25.1 |
| Three | 14.8 | 16.2 | 13.3 |
| Four | 14.3 | 11.6 | 7.3 |
| Five or more | 44.9 | 23.4 | 10.4 |

Six of the ten most often prescribed drugs for the older-old are cardiovascular drugs (antihypertensives, digoxin, potassium supplements). Beta-blockers represent 17.8% of cardiovascular drug use for community-living elderly (over 35% for those less than 65 years of

age) but only 4.4% for nursing home residents. Major tranquilizers represent 12.5% of all psychotropic drugs used for community-living elderly, but they account for almost 61% of all psychotropics used for nursing home residents (Table II):

TABLE II
Specific Drug Categories

| Drug Category | 65+/NH (%) | 65+ non-NH (%) | 65- (%) |
|---------------------|------------|----------------|---------|
| Cardiovascular | | | |
| Beta-blockers | 4.4 | 17.8 | 35.2 |
| Ca antagonists | 2.9 | 8.6 | 8.6 |
| Vasodilators | 29.5 | 26.5 | 16.2 |
| Digitalis | 29.2 | 12.5 | 5.4 |
| Psychotropics | | | |
| Antipsychotics | 60.5 | 12.5 | 14.8 |
| Anti-anxiety agents | 17.1 | 59.0 | 51.0 |
| Antidepressants | 12.3 | 16.0 | 18.1 |

The prevalence of antipsychotic drug use apparently varies widely among nursing homes, usage increasing with nursing home size and being inversely related to the ratio of nursing home staff to patient.

The use of psychotropic drugs for nursing home residents is also mirrored in a listing of the top 8 drugs used (Table III):

TABLE III
The Most Often Prescribed Drugs

| Rank | Over 65/NH | Over 65/non-NH | Under 65 |
|------|------------------|------------------|-------------------|
| 1 | Digoxin | HCTZ/triamterene | Codeine/APAP |
| 2 | Furosemide | Digoxin | Amoxicillin |
| 3 | Potassium Cl | Potassium Cl | Norethrin/ethinyl |
| 4 | Dipyridamole | Nitroglycerin | HCTZ/triamterene |
| 5 | Nitroglycerin | Furosemide | Penicillin V Pot |
| 6 | Haloperidol | Dipyridamole | Ibuprofen |
| 7 | Thioridazine | Propranolol | Theophylline |
| 8 | HCTZ/triamterene | Codeine/APAP | Estrogens |

The two antipsychotics (haloperidol and thioridazine) which rank high in use for nursing home residents rank only 99th and 90th for community-living elderly.

Six of the top 12 diagnoses and the top 12 drug groups for patients over 65 in 1986 were cardiovascular, with the top 12 representing 54% of all diagnoses and 64% of all drug therapy (the two drug categories whose use increases with increasing age are the cardiovascular drugs and the nonsteroidal anti-inflammatory drugs).

Possible Future Changes

Major changes (and concomitant cost increases?) are anticipated in the field of hypertension management. For example, a committee of the American Society of Hypertension (ASH), chaired by Dr. Norman Kaplan, reported at the 1987 meeting in New York that selection of a diuretic in the step-care approach to the

management of hypertension seems increasingly inappropriate and outdated. For most patients, treatment should begin with a single agent, selected empirically or on the basis of age, race, coincident conditions such as hyperglycemia or hyperlipidemia, or by renin profiling.

Among antihypertensive drugs, the use of ACE inhibitors and calcium antagonists is rising fast (in the overall market). For example, first-quarter (1987) sales for calcium antagonists were \$146 million, up 24% from the same period in 1986.

Prescription Drugs: Still Cost Effective

In general, prescription drugs are still relatively inexpensive compared to more labor or technology intensive modalities of health care. They are and remain the front line of medical care for the elderly and are probably most cost effective. For example, the use of cimetidine to control duodenal ulcers resulted in an estimated 26 to 70% saving for Medicaid in Michigan in its first year of use by reducing the need for surgery. Similarly, it has been estimated that lithium treatment of manic-depressive illness has saved \$4 billion during the last decade.

Enrollment in a pharmaceutical assistance program in New Jersey, following the establishment of that program, was associated with a reduction in expenditures for hospital-based procedures. This latter point is of extreme importance. Of the 27 million elderly, approximately 25% can probably expect to be stricken with cancer. Antineoplastic agents are covered only when patients are cared for in a hospice or are hospitalized. The daily hospital rate is probably \$350/day. A vial of one antineoplastic (chemotherapeutic) agent may be \$90 and the patient may need two to three vials of just this one agent. This does not take into consideration pre-treatment activities, such as hydration, for example. Thus, patients are often hospitalized in an effort to protect them from high drug expenditures. Yet, these drugs could be administered in the home at considerable savings to the system.

ONE OUTCOME OF MULTIPLE DRUGS USE: ADVERSE DRUG REACTIONS

Prevalence of Adverse Drug Reactions

There is no agreement as to the frequency of adverse drug reactions. One study (*N Engl J Med* 304:638, 1981) showed that 36% of patients on a general medical service has an iatrogenic illness, often due to drugs. Another (*N Engl J Med* 291:824, 1974) showed that these undesirable reactions occur most often in patients receiving multiple drugs. Deaths attributed to drugs occurred at a rate of 2.4 per 1000 patients (*J Allergy Clin Immunol* 74:555, 1984). The FDA expects reports to increase sharply (in 1986: 57,000 reports, a ten-fold increase over the last 5 years, going to over 100,000 in a few years). Most involve well-known drugs. One-third

of all ADR hospitalization reports involved elderly, as did over 50% of all death reports. Thus, elderly are more susceptible to adverse drug reactions and to their effects.

Drug interactions occur more often in elderly than in younger patients. They occur most often in long-term care institutions and in patients with multiple pathology receiving multiple drugs.

Some Results of Adverse Drug Reactions

One example of a potential problem of geriatric drug therapy, in the presence of multiple pathology and concurrent drugs, will be used to highlight the risk to which elderly patients may be exposed. Drugs used to treat several diseases and problems can cause dementia. Many drugs that block the effect of acetylcholine, either as a primary (desired) effect or as an undesired (adverse reaction) effect, are used in the treatment of Parkinson's disease, insomnia, hypertension, colds, depression, and psychoses. Drug-induced dementia is even more common as a cause of reversible dementia than is depression. Indeed, drugs are the most common cause of a syndrome that has been labeled "pseudo-dementia".

Side effects of medications, especially "minor" symptoms, reduce the cost-effectiveness of chronic disease management to a considerable degree. Therefore, diminishing negative side effects of medications and improving the patient's and caregiver's quality-of-life satisfaction are and must be essential goals of chronic disease management. This demands an intimate knowledge of a drug's action, which is perhaps lacking at times.

While quality-of-life has been an important parameter of clinical decision-making for severe diseases (cancer, renal failure) for some time, it has now been recognized that, given the high prevalence of chronic disabilities among the older population, patient adherence to an agreed-upon regimen, linked to quality-of-life perceptions, must have a high health policy priority.

The need for this priority is still not universally recognized. For example, in the general population, in 1984, there were more than 125,000 deaths and several hundred thousand hospitalizations due to noncompliance with cardiovascular drugs alone (six of the 10 most frequently used drugs for patients 75 years old and over are cardiovascular drugs). In addition, approximately 20 million work days were lost representing an overall cost of \$1.5 billion to the national economy simply because prescribed cardiovascular drugs were not taken properly. HHS Associate Secretary Robert Windom and FDA Commissioner Frank Young have termed this "the other drug problem". They have stated that up to one-half of the 1.6 billion prescriptions each year are taken improperly. Pharmacists' (and other health care specialists') intervention and compliance efforts have proven that this problem can be alle-

viated to a large degree. Efforts, though, are limited due to lack of reimbursement policies.

Possible Reasons for Adverse Drug Reactions

A major problem is the lack of a sufficient knowledge base. The problem of insufficient knowledge and education about geriatrics and gerontology is global, affecting both human services and medical fields. While it is accepted that drugs are the most cost-effective modality of chronic disease management (OTA, 1985), very little is known about altered drug action in the elderly, particularly the very old, especially in the presence of multiple pathology and multiple drug use (which is often the rule, rather than the exception).

In part, that lack of knowledge can be explained by the fact that rates of functional decline (aging) vary enormously from person to person and from organ to organ within a single person. To some degree, though, "insufficient knowledge" in fact relates to "insufficient dissemination" of current knowledge and its application to geriatric practice (Table IV) and a continuing "traditional approach" to the elderly patient, which uses chronological age as a basis, rather than "functional", "socio-economic", or "dependency" status (Table V).

Finally, insufficient knowledge about drugs must be related to the fact that studies on drug use and drug action in the elderly are largely lacking, having taken a back seat to studies elucidating the reasons for aging and similar topics.

Among other reasons for adverse drug effects and interactions in the elderly are physiological and pathophysiological changes with age, multiple drug use, mismanagement of drugs by both providers and patients (as well as caregivers) and poor supervision. Mismanagement of drugs can be expected to increase in view of

the fact that the home care segment is the fastest-growing segment of health care for the elderly. According to the Royal College of Physicians (J R Coll Phys 18:7, 1984), supervision of chronic care medications is poor, accounting for many adverse effects and, according to the US College of Physicians (Ann Intern Med 105:454, 1986), physicians too often do not participate in home care.

RECOMMENDATIONS FOR CONGRESSIONAL ACTION

Background Considerations

Congress is currently involved in discussing reimbursement of drugs for ambulatory elderly under Medicare while, at the same time, considering coverage of catastrophic illness. Congress is also requiring the HHS Secretary to revise Federal rules governing nursing homes, to improve the quality of care and the protection of patient's rights. This action follows a report, in 1986, by the Institute of Medicine, an arm of the National Academy of Science. The report found that patients received "shockingly deficient" care in many nursing homes that receive Federal funds for Medicare and Medicaid patients. The Institute noted that patients in these homes were "likely to have their rights ignored or violated and may even be subject to physical abuse". Congress subsequently perceived correctly that new statutory standards for nursing homes are needed.

TABLE V
New Approaches to the Aged

| Disease Specific Approach | Old | New |
|---------------------------|-----|---|
| | | Care Objectives Intervention Options |
| | | |

TABLE IV
Age-Related Changes and Their Possible Effects on Action of Antihypertensives

| Organ/System | Change with Age | Possible Effect |
|----------------|--|--|
| Brain | Cerebral blood flow decreased by 25%. Cerebral autoregulation impaired. Increased permeability of blood/brain barrier | Use drugs that preserve cerebral blood flow. Caution: hyperfusion (?) stroke (?) Exaggerated CNS effects by lipid-soluble drugs: clonidine, methyldopa, metoprolol, propranolol |
| Cardiovascular | A poor homeostatic system. Impaired control and vascular reactivity. Deterioration of conducting system. Between ages 20 & 80, a 90% loss of vessel elasticity & distensibility Baroreceptor sensitivity decreased. Vascular aging (aortic arch), attenuated beta-adrenergic response, blunted postural reflexes, decreased body water, varicose veins, etc. | Caution: drugs that interfere with cardiac impulse (beta blockers). Greater fall in BP with decreased in blood volume. Increased risk to hypotension, hypovolemia Altered compensatory mechanism drug induced fall in BP. Increased risk to drug-induced orthostatic hypotension. Caution with diuretics, ganglionic blockers, vasodilators |
| Renal | By age 80, GFR decreased by 25%. Renal blood flow by 50%. Tubular function decreased by 7% per decade | Ability to adjust sodium balance is decreased. Caution: sodium depleting drugs, reduced dietary intake. Increased danger to diuretic induced water intoxication, hyponatremia. May have to reduce dose of renally excreted drugs. Defective thirst mechanism and impaired renal concentrating ability: higher risk to dehydration. |

One of these rights, although not stated explicitly nor alluded to, is the rational and correct use of drugs in the management of chronic diseases. Perhaps these hearings can serve to facilitate a new statutory approach to this problem in a manner similar to the facilitating effect that the IOM report had.

To achieve this end, it is likely that a multifaceted approach is needed, i.e. the creation of a data base, its evaluation, and the development and dissemination of educational materials based on the continuously updated data base. Finally, and most importantly, there needs to be a continuous quality-of-care review of the therapeutic outcome of drug use.

While the FDA still has not mandated testing of drugs in the elderly after several years of hearings and proposals, one would assume that it will do so soon. That, alone, will not serve to ameliorate the problem. This will address only characteristics of new drugs and most of the problems of drug use revolve around old and well-known drugs. Congress has several options to create a better therapeutic milieu for elderly persons needing medications.

Focus on Home Care: The Nursing Home Without Walls

Home care is the fastest-growing sector of health care for the elderly. As previously pointed out, for every elderly nursing home resident, there are already four adults living in the community of equal age with similar medical problems, but more serious problems in socio-economic support. Dr. Butler, some time ago, suggested the creation of the "Teaching Nursing Home". The nursing home population will remain static, not least because there will be a shortage of nursing home beds and nurses. Thus, creation of the concept of the "Teaching Nursing Home Without Walls" must be a major priority. It will correlate well with NIA's call for an interdisciplinary, community based long-term care system.

It is important to point out here that management of drugs is more difficult in this sector than in the more structured nursing home sector. One approach to ameliorate this problem might be funding of "compliance packaging". The United States Pharmacopoeia has approved "Med-Pak". Studies have shown that over 20% of all admissions of elderly to nursing homes are due to the elderly patient's inability to self-administer medications. Medicaid has consistently refused to reimburse for packaging which will, among other benefits, enhance a patient's ability to remain at home by making it easier to self-administer medications. This packaging could also be used to create a data base on actual use of drugs and for drug utilization review.

Evaluate, Support and Expand the Role of the Pharmacist

In 1974, the Federal government mandated that pharmacists review, on a monthly basis, the therapeutic regimen of all federally-financed SNF patients. In a Re-

port to Congress, entitled "Problems Remain in Reviews of Medicaid-financed Drug Therapy in Nursing Homes" (June 25, 1980), the Comptroller General found these services effective clinically and economically, but also pointed to the need for an expanded data base. HCFA, in 1987, expanded the role of pharmacists to include ICF patients, but the problem of a knowledge base remains.

In the meantime, requests to the HHS Secretary have pointed to the need for the same function in the home care sector, since many of these patients suffer from problems very similar to those seen in the nursing home sector.

The problems of the knowledge base has been addressed by Pharmacy in several ways. One was the publication by the American Association of Colleges of Pharmacy of the text "Pharmacy Practice for the Geriatric Patient", which is being used by many Schools of Pharmacy for teaching and continuing education purposes. A different approach was used by the University of Maryland School of Pharmacy, which, funded by the Andrus Foundation, originated and presented a 32 hour training program on geriatric drug use for rural pharmacists. About 200 pharmacists participated in the states of Maryland, Virginia, West Virginia, Delaware, and Pennsylvania. The cost was approximately \$15.00/pharmacy practitioner/hour. It is of note that the NIA has not supported any Pharmacy effort so far, though the AoA has. It is noteworthy that the State of Pennsylvania has addressed the School of Pharmacy with a request to offer this program on a wider basis in that state.

But Pharmacy's role in achieving rational and correct use in long term care is greater than that suggested by its service role. At a recent meeting on geriatric pharmacology in Baltimore, co-sponsored by the NIA, it was reported that much of the teaching functions in geriatric clinical pharmacology programs were performed by pharmacists. Yet, the NIA has to this point not supported any training programs for pharmacists similar in scope and nature to those developed for physicians and dentists. Indeed, it has never appointed a pharmacist to its National Advisory Council. The NIA should be directed to address these issues urgently, while HCFA should be directed to study the need for therapeutic regimen review in the home care sector.

Creation of a Continuously Updated Data Base

Congress should encourage and require increased post-marketing surveillance of drug use. Federal funds are supporting Medicaid patients to a considerable degree and Congress should require that the data base available through Medicaid funding of prescription drug use be made available to qualified pharmacoepidemiologists. To a degree, individuals have already used these data, but only to a small degree. One outcome, for example, although it did not and could not show cause and effect, is the realization that certain beta

blockers probably cause more CNS problems in the elderly than others.

While the Medicaid data base is probably the most promising and the largest, other likely data bases should not be overlooked. For example, data bases created by large nursing home chains might be available, as may be those from large mailorder prescription operations. Furthermore, it has been estimated that, in a relatively short time, almost 50% of the US population will receive health care from a "managed care" system, which is likely to have access to a large, specific data base (Puget Sound, for example).

An Example How This Data Base Could be Created

Using the School of Pharmacy, University of Maryland, as an example, one could suggest the following sequence: Drug Policy Center: Recently established at the School of Pharmacy, its Associate Director, Dr. Palumbo, has completed the second of two major federally-financed studies on drug use in nursing homes. The Center is a joint effort of the School of Pharmacy and the UMBC Policy Sciences graduate program. This unique combination places the Center in an ideal position to respond to and evaluate problems such as those being addressed. The Center could be charged (with appropriate funding) to collect Medicaid and other data on drug use in the long-term care sector and analyze these data. The data base would then be evaluated in conjunction with The Center for the Study of Pharmacy and Therapeutics for the Elderly: Established some eight years ago, the Center has as its primary function the facilitation of gerontological research (Pharmacology, Pharmaceutics). A second, and major, function of the Center is the development of educational programs. It discharges that responsibility in several ways. One is the collection and dissemination of appropriate information through its ElderCare Newsletter, which now reaches approximately 29,000 health care professionals (see attachment). Through its Parke Davis Center for the Education of the Elderly, it has developed and continues to do so, pamphlets directed to the consumer, which aim to educate the consumer on various aspects of drug use, nutrition, as well as preventive care. The Parke Davis Center has also developed two major audiovisual tapes, describing drug use for the elderly and the elderly's concerns, both of which have been shown on national television in some 40 states. Finally, through its Elder Health Program, which has received an Award of Merit from the HHS Secretary, it addresses consumers directly. This program has been replicated in many states.

The Center also addresses educational needs of professionals by originating and presenting continuing education programs on a local, state, national, and international level. Furthermore, the Center supports several residencies and fellowships (in long-term care, home care, and drug dosage development for the elderly).

The Center would refer back to the Drug Policy

Center appropriate information for formulation of policy recommendations.

Funding and Oversight

It is proposed that efforts such as those outlined above be funded and supervised by the National Institute on Aging. While it is realized that this may not necessarily conform to the charge the NIA originally received, these efforts are of sufficient importance to be addressed by the premier organization in aging.

It is further strongly suggested that the NIA appoint an oversight committee different from its current National Advisory Council. It is suggested that the NIA is deficient in its approach to drug use (perhaps because there is not a pharmacist either on its staff or on its committee). Pharmacy-educated and prepared practitioners, long charged by the Federal government with review of nursing home patients' medication regimen, would likely add a much different dimension to these efforts.

This recommendation, if enacted, is in concordance with the NIA call for an interdisciplinary, community-based long-term care system. It would then have the means to help originate and coordinate such a system.

Written Testimony prepared for hearings, 20 July 1987, by the Senate Special Committee on Aging, Senator John Mecher (D-Mont), Chairman.

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly; Director, The Parke Davis Center for the Education of the Elderly; Chairman, Department of Pharmacy Practice and Administrative Science, School of Pharmacy and Research Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD 21201. Dr. Lamy is a Fellow, American Geriatrics Society; a Fellow, The Gerontological Society of America; a Fellow, The American College of Clinical Pharmacology; a Fellow, American Association for the Advancement of Science; and a member, American Society of Clinical Pharmacology and Therapeutics.

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AACP'S PERSPECTIVE ON THERAPEUTIC INTERCHANGE

INTRODUCTION

While therapeutic interchange is a topic with a high degree of current interest, it shrinks somewhat in importance when viewed as a component of the clinical practice of pharmacy. However, since participation in therapeutic decisions is an essential element of the clinical education that all students in entry-level professional pharmacy programs are trained to perform, the AACP Board of Directors recently voiced its support of ". . . the concept of therapeutic interchange of various drug products by pharmacists under arrangements in which pharmacists and authorized prescribers interrelate on behalf of the care of patients."

The existence of considerable debate and rhetoric over therapeutic interchange indicates that significant confusion exists about this concept in the minds of many persons. This statement is intended to define and clarify AACP's position on therapeutic interchange and the involvement of pharmacists in that process.

DEFINITION

AACP continues to support the definition of therapeutic interchange described by its Board of Directors. This concept is not new and it does not reflect a significant change in direction for the profession of pharmacy. It merely makes explicit the growing partnership between prescriber and pharmacist that is occurring in the real world of health care, particularly in organized settings such as hospitals, long term care facilities, and managed ambulatory health care systems. These professionals increasingly recognize and act upon the realization that both share a common goal: providing patients with optimal drug therapy at an affordable price.

Therapeutic interchange does not mean that pharmacists substitute their judgment for that of prescribers. It does mean that willing pharmacists provide information and advice to willing prescribers, resulting in drug therapy decisions more appropriate to patient needs than decisions either could have achieved alone.

Therapeutic interchange is not therapeutic substitution, it is therapeutic synergism; it flows from the voluntary combination of the knowledge and skills of two complementary professionals.

THE ISSUES

Therapeutic Interchange and the Law

Since therapeutic interchange, by definition, involves the interrelationship of pharmacists and prescribers, no radical changes in pharmacy practice acts are required to permit it. Some states have enacted or proposed legislation to require physician involvement in the development and supervision of protocols to guide therapeutic interchange. In some cases this legislation calls for the establishment of arrangements similar to those used in hospitals, such as pharmacy and therapeutics committee supervision of drug selection and use in the institution. While this type of regulation is consistent with the concept of therapeutic interchange, it is not necessary to permit it.

Some state legislative proposals are negative in that they seek to prohibit unilateral therapeutic substitution by pharmacists. Since neither AACP nor any other pharmacy organization advocates such unilateral action by pharmacists in the area of drug selection, the enactment of such prohibitions would in no way limit therapeutic interchange as defined here. However, this type of legislation would be redundant, since current practice laws already prohibit unauthorized therapeutic substitution by anyone.

Therapeutic Interchange and Pharmacist "Prescribing"

Prescribing may be defined as the independent authority to order a legend drug for a specific patient. This function is clearly different from that of engaging in therapeutic interchange, and the two concepts should not be confused.

Therapeutic Interchange and a Third Class of Drugs

The only state in the nation that permits a situation approximating pharmacist "prescribing" is Florida, which has established a group of legend drugs that can be dispensed by pharmacists upon request of the patient. The Florida legislation in effect has created a third class of drugs in the state. The legislation does not give pharmacists the unilateral authority to change a

prescriber's drug order, nor does it in any way address prescribing by physicians. The law has no bearing on the concept of therapeutic interchange.

Therapeutic Interchange and Therapeutic Substitution

Arguments have been developed by some individuals and groups defining therapeutic substitution as the practice of dispensing a drug entity, different from that prescribed, without the knowledge or authorization of the prescriber. It is clear to AACP that this approach to therapeutic decision making enjoys very little support among pharmacists. Indeed, while several pharmacy organizations have adopted policies supporting therapeutic interchange, no organization advocates independent authority to dispense a different drug entity from that prescribed absent the knowledge and approval of the prescriber.

Unfortunately, many of the position papers and analyses condemning therapeutic substitution have not distinguished between it and therapeutic interchange. As a result, this has led to unwarranted criticism of pharmacists moving into the arena of therapeutic interchange. AACP views initiatives to prohibit therapeutic interchange to be counterproductive and confusing because this criticism strikes at an important element of the clinical practice of pharmacy.

Practice Settings

Therapeutic interchange has long been practiced in the nation's hospitals. Arrangements such as formularies and drug therapy protocols, under the supervision of a pharmacy and therapeutics committee made up of both pharmacists and prescribers, have a long and successful record in the inpatient setting. In fact, the cooperation of pharmacists and prescribers to improve patient drug therapy in the hospital settings is perhaps the most outstanding example of a well-functioning, interprofessional health team in all of health care. A significant body of well-designed research exists that attests to improvements in drug therapy and thus improvements in the quality and economy of patient care resulting from the synergistic cooperation of pharmacists and prescribers compared with prescribers practicing in the absence of pharmacist collaboration.

Recent advances in the organization of ambulatory health care services through managed care systems such as health maintenance organizations are making it possible to build the benefits of clinical pharmacy, and its related activities such as therapeutic interchange, into settings other than the traditional institution. Improved computer-based information and communication techniques make it possible for pharmacists and prescribers to share patient information in ways not previously possible in ambulatory settings. Thus, efforts are underway to develop mechanisms to routinely engage in therapeutic interchange when treating outpatients.

AACP supports these efforts as long as the basic precept of therapeutic interchange is met: an arrangement in which pharmacists and prescribers interrelate on behalf of the care of patients.

Turf

Some have viewed pharmacy's advocacy of therapeutic interchange as a desire to invade the prescriber's turf and to expropriate a function exclusively the physician's because of education and access to more complete patient information. Such a view is incompatible with the concept of therapeutic interchange espoused here.

Therapeutic interchange cannot work without the complete and voluntary commitment of all parties to make it work. Without this voluntary commitment on the part of both pharmacists and prescribers, efforts to mandate therapeutic interchange would be fruitless. Thus, AACP advocates the concept of therapeutic interchange, believes it makes exquisite sense, and supports the education of pharmacy students to perform the function competently.

Economics

Widespread implementation of the concept of therapeutic interchange explicitly recognizes the pharmacist as a critical participant in drug therapy decisions. While this has been the case for years in the institutional setting, it is relatively new in the ambulatory care setting. Anything new is threatening to some, and it is clear that the emergence of the pharmacist in this role is seen as threatening to the marketers of brand-name drugs. It is not difficult to understand why. The marketplace for prescription drugs has been buffeted by several changes in recent years: the shift to prospective hospital reimbursement, the growth of alternative delivery systems, and pressures for cost containment. Adding the pharmacist to the decision-making process means another type of professional the drug marketer must deal with—a professional who is, by virtue of education and experience, much more sophisticated than prescribers on many aspects of the drug selection process.

It appears that opposition to the concept of therapeutic interchange by representatives of the industry is grounded basically upon economic concerns. AACP believes, however, that most firms will be able to emerge from the concern stage with revised marketing plans that incorporate the pharmacist as an important decision maker to be addressed. A similar pattern emerged after laws in all the states were revised to permit pharmacist involvement in drug product selection of generics over a decade ago. AACP is committed to working with the pharmaceutical industry in strengthening the process by which drugs are selected.

SUMMARY AND CONCLUSIONS

Therapeutic interchange has become a topic of unwarranted controversy. This paper has pointed out that the concept simply embodies closer cooperation between prescriber and pharmacist in making patient drug therapy decisions, in all settings, that permit free and complete communication about the patient. This cooperation, voluntarily entered into, will naturally result in better drug therapy, and that is an outcome that all parties should agree is desirable.

AACP and pharmaceutical educators support the concept of pharmacy as a clinical profession, an essential element of which is the concept of therapeutic interchange. Further, AACP believes that therapeutic interchange is in the interest of better health care. We teach our students how to engage in therapeutic interchange and advocate its implementation where ever possible. We oppose efforts to limit the ability of pharmacists to engage in such cooperative efforts with prescribers.

* Adopted March 7, 1987. Similar statements have been adopted by ACA, APhA, ASCP, and ASHP.

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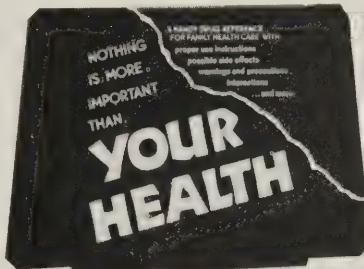
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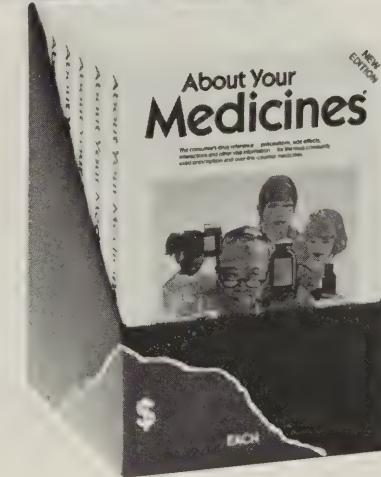
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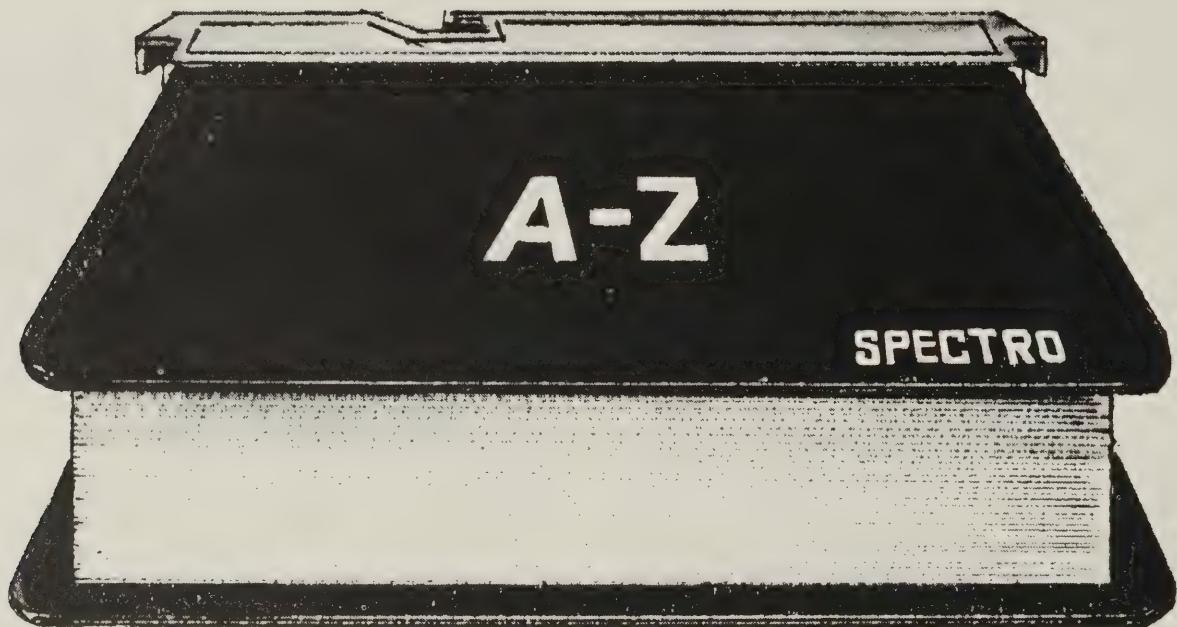
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by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

Treatment Measures for Decubitus Ulcers

Pressure sores remain one of the most persistent problems facing a hospice team. Terminally ill patients are difficult to treat because they frequently do not turn as much as necessary to prevent sores from developing. In addition, many hospice patients eat poorly or have inadequate fluid intake, leading to dehydration and skin breakdown.

Other factors may also contribute to ulcer formation. Direct pressure from the weight of the body against its supporting surface is one such factor. Pressure decreases blood flow, especially over bony prominences. If the surface is hard, as it is with plastic hospital mattresses, bedpans and wheelchair seats, the flow of blood is interrupted even more quickly. Unrelieved pressure to the skin and soft tissue (as early as 2 hours) will increase interstitial pressure and cause venous and lymphatic obstruction, resulting in autolysis and accumulation of anaerobic metabolic waste and finally skin breakdown.

Shearing forces also cause damage by stretching or pulling of the tissues. Such forces can occur, for example, by a patient slouching in the wheelchair. This has the effect of undermining the dermis and causing thrombosis of the vessels. Friction occurs when the pa-

tient is moved or dragged, especially across a harsh support. It can cut off the blood supply as well as abrade the skin. Both friction and shearing can contribute to the development of pressure sores.

Moisture problems are another contributing factor to the development of decubitus ulcers. Perspiration, urine and feces all can cause maceration of the skin.

The best treatment for bedsores is *prevention*. There are many measures that can help to prevent ulceration, but unfortunately they don't always work. Pressure sores can be relieved by frequent turning of the patient (every 1–3 hours), bridging with pillows, special mattresses, elbow pads, heel pads or sheepskin. Friction and shearing can be avoided by proper positioning. Cleanliness and keeping the areas dry will help with moisture problems.

A nutritional approach is also important in management. Malnourishment leads to emaciation, which in turn leads to bedsores. Malnourishment also causes anemia which decreases the body's ability to heal existing sores. A sound nutritional program, therefore, is necessary to help maintain and form tissue (one which replaces fluid and protein loss and corrects anemia and dehydration). Patient and care-giver education is im-

portant in all of this.

When prevention does fail and a pressure sore develops, it must be kept meticulously clean. Hardened, necrotic matter which is present must be debrided daily to prevent infection. This can be done with normal saline gauze dressings, applied several times a day. Other agents which may be recommended are Betadine or Hibiclens (drying agents; anti-infective), used as 1/2 strength with normal saline. If the skin is broken, a dressing may be necessary. Impermeable or semipermeable membranes (DuoDerm, Opsite, Tegaderm) may also be useful adjuncts if incontinence or fecal soiling is a problem. Medicated dressings are sometimes needed (Silvadene).

Dry sterile dressings should be applied to protect open wounds or blisters. Protective skin barriers (tincture of Benzoin or skin prep) may be needed around the dressing before the tape is applied. Alcohol, soap and Phisohex are *not* recommended for an open wound because they all destroy new epithelial cells. Hydrogen peroxide is sometimes used as an irrigant in a 1/4 strength solution. It is only used for dirty wounds and must be discontinued once the wound is clean (it too causes epithelial cell destruction in this situation). Acetic acid solution 0.25% can be used as an irrigant, and is particularly useful in wounds infected by pseu-

duomonas, candida or trichomonas. Normal saline rinses should follow either of these irrigating solutions.

After debridement and cleaning, healing of an ulcer may be hastened by packing it with a wet dressing. The saline dressing should be changed after drying (4-8 hours). Kling gauze or a sterile 4 x 4 soaked in warm saline (run bottle under hot water) is packed fully in the wound. Dry 4 x 4's and an ABD pad is then applied to cover the area which is shut by Montgomery straps.

An excellent review of the above procedure and other wound management guidelines is found in the American Journal of Nursing (August 84; 999-1003). This article defines the stages of pressure sores and explains the rationale for the supportive and physical measures taken in treatment procedures, and would be an excellent reference article to be used in patient/family education.

Special Note: When appropriately prescribed by a physician, water mattresses and alternating pressure pads may be reimbursable by Medicare and most other insurers.

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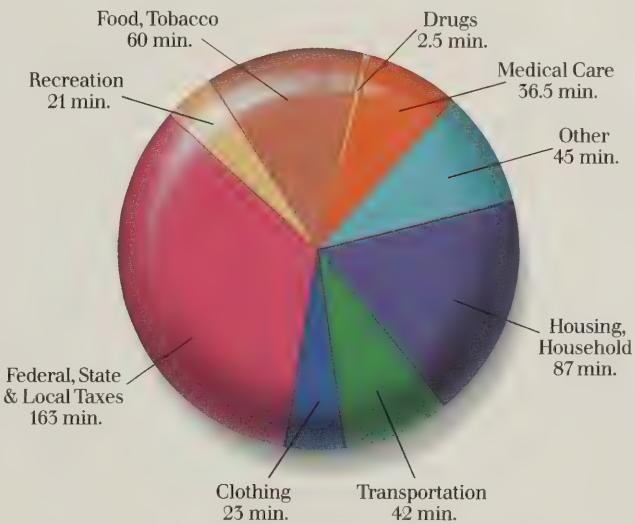
The Vice Speaker of the House of Delegates, Ilene Zuckerman, also serves as Chairman of the Association's Resolutions Committee. The Committee will be meeting soon to consider issues and resolutions for the Annual Convention of the Association, June 19–23, 1988 in Ocean City, Maryland. In order to allow for greater membership participation in the resolution process which forms the basic policy making structure of the Association, the Committee is soliciting input from the membership in the form of suggested resolutions or resolution topics. Resolutions may be sent to the Association at this time with any background or supporting information necessary. They should be sent to the M.Ph.A. Resolutions committee, 650 West Lombard St., Baltimore, Md. 21201.

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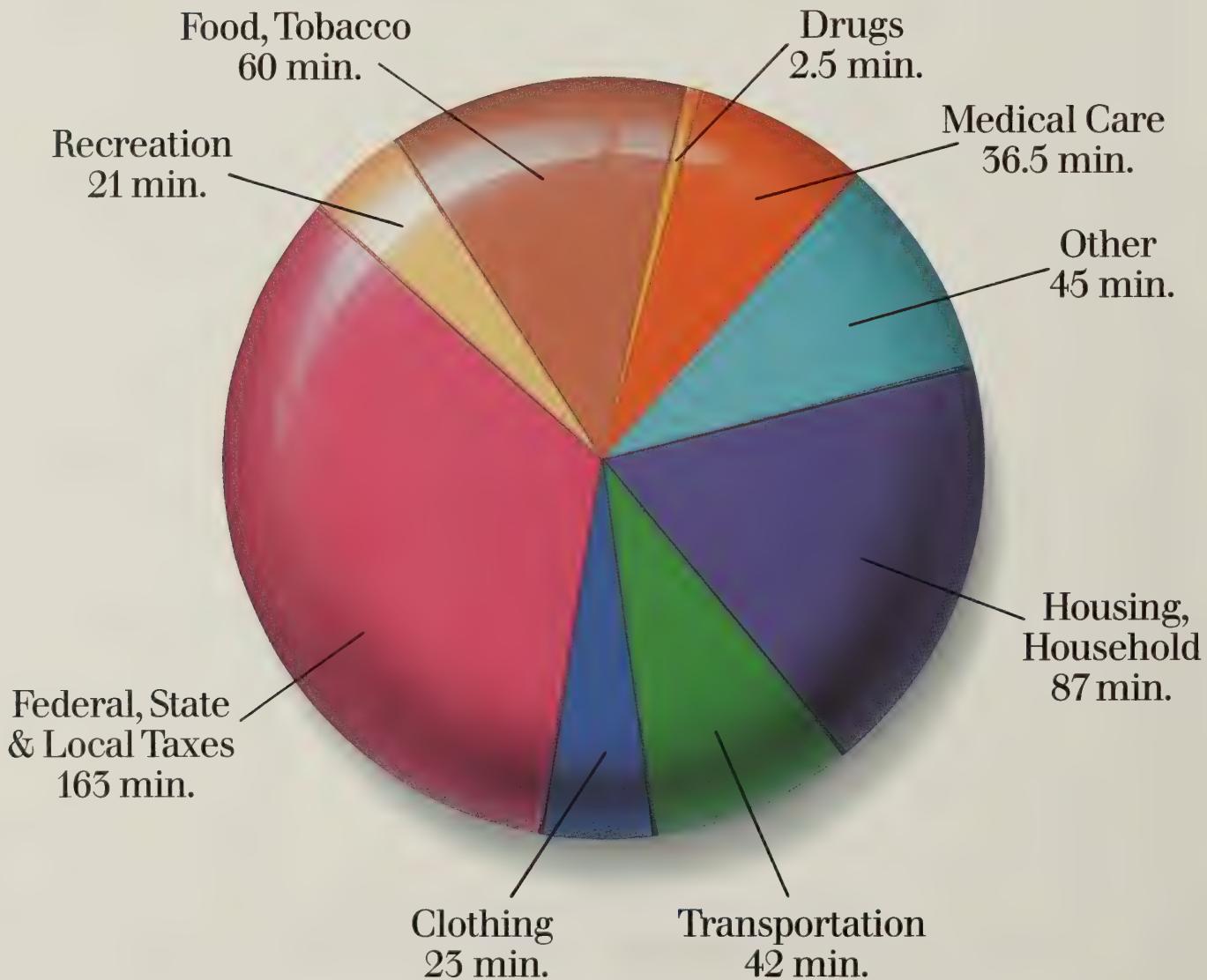
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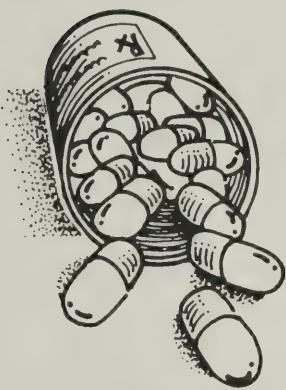
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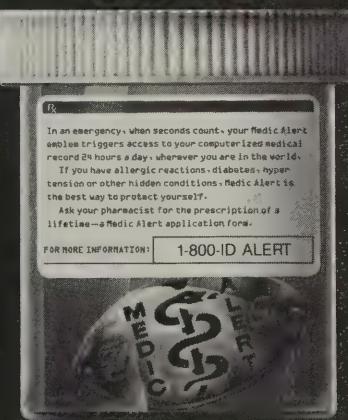
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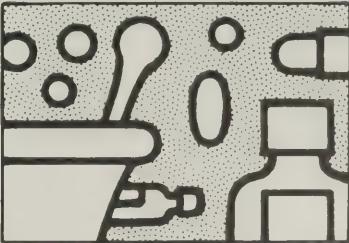
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Things You Should Know FOR YOUR GOOD HEALTH



Obesity is a Weighty Factor in the Risk of Diabetes

American parents for years have been warning their children about eating too many sweets. "You'll wind up with diabetes" is the bleak prediction. That, in the eyes of most experts, is a lot of nonsense; a preconceived notion that has never been proven.

There are however, established factors that put some people at a good deal more risk of developing diabetes than others. The main predisposing factors to the development of diabetes are heredity and obesity. Race, age and gender are less certain predictive indicators for this condition. Obesity is the only condition which you can do anything about. But, what is obesity and who is obese?

Obesity is simply an excess of body fat frequently resulting in a significant impairment of health. Many experts believe that if an individual is 20 percent or more above desirable body weight, he or she should seek medical help to reduce weight and thereby, potential health risks.

It is important to recognize the two types of

diabetes and obesity's impact on each type. The most common type of diabetes in this country is non-insulin-dependent diabetes (NIDDM) which affects about 90 percent of all diabetics in the U.S. The NIDDM type usually strikes after 40 years of age. In contrast, the other major type of diabetes, which leaves the patient completely dependent on insulin injections for survival, generally shows up in the early years. In fact, it is sometimes called "juvenile-onset" diabetes.

Obesity is a risk factor only for non-insulin-dependent diabetes. This is of particular concern in the U.S. because, according to a National Health and Nutrition Examination Survey, about 34 million people between the ages of 20 and 75 are significantly overweight.

So what can we do to control at least one factor to help prevent diabetes? The answer is simple: diet and exercise. However, special caution should be taken before embarking on any restrictive diet or new exercise program. Consult a physician, dietitian, or pharmacist for health related information.



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The "Wheel of Health" Game

Read the clue for each group of words or phrases. Then fill in the missing letters to solve the puzzle.

A. Uncontrolled high blood pressure can lead to:

1. __ EA __ A __ A __

2. S __ O __ E

3. __ I __ E
__ AI __ U __ E

B. Things you should do to control your high blood pressure:

4. E __ E __ I __ E
__ E __ U __ A __ L __

5. FO __ OW
__ O __ TO __
O __ E __ S

6. CO __ RO __ OU __
__ EI __ H __

7. SEA __ O __ WI __
HE __ S __ IN __ EA __
O __ AL __

- | | |
|---|---|
| 8. MA __ E A CO __ MI __ ME __ T | 25. well-being 24. healthy 23. therapy 22. checkup 21. control 20. lifetime 19. commitment 18. medication 17. prescription 16. hypertension D. Key words to remember when controlling your high blood pressure: |
| 9. FO __ O __ OU __ RE __ I __ E __ A __ Y | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 10. SE __ GOA __ | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 11. TA __ E YOU __ __ IL __ | 3. kidney failure 2. stroke 1. heart attack sure can lead to: A. Uncontrolled high blood pressure can lead to: |
| 12. EA __ F __ ES __ F __ UI __ A __ D VE __ ETA __ ES | 25. well-being 24. healthy 23. therapy 22. checkup 21. control 20. lifetime 19. commitment 18. medication 17. prescription 16. hypertension D. Key words to remember when controlling your high blood pressure: |
| 13. __ A __ I __ Y | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 14. F __ IE __ | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 15. __ OU __ O __ TO __ | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| D. Key words to remember when controlling your high blood pressure: | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 16. __ Y __ E __ TE __ OI __ | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 17. P __ ES __ I __ OI __ | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 18. __ E __ I __ A __ OI __ | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 19. CO __ MI __ E __ T | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 20. __ I __ E __ I __ E | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 21. CO __ O __ | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 22. C __ EC __ U __ | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 23. T __ E __ A __ Y | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |
| 24. HEA __ | 15. your doctor 14. friends 13. family sure: C. People who will be happy if you control your high blood pressure: |
| 25. WE __ L __ EI __ | 12. eat fresh fruits and vegetables 11. take your pills 10. set goals 9. follow your regimen daily 8. make a commitment 7. season with herbs instead of salt 6. control your weight 5. follow doctor's orders 4. exercise regularly sure: B. Things you should do to help control your high blood pressure: |

"Wheel of Health" Game:

Answers to

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Maryland Society of Hospital Pharmacists Meetings

MARK YOUR CALENDARS, PLEASE:

The 1987-1988 MSHP Roster of Monthly Programs is under development. Please note the following dates and sites on your calendars:

| | |
|-------------------|------------------------|
| FEBRUARY 11, 1988 | —TBA (To Be Announced) |
| MARCH 10, 1988 | —TBA (To Be Announced) |
| APRIL 14, 1988 | Mercy Hospital |
| MAY 12, 1988 | Johns Hopkins Hospital |

PHARMACY SCHOOL NATIONAL TOLL FREE PHONE LINE. The school of Pharmacy has acquired a new national toll free phone for Admission and Registrar department. The number is 1-800-852-2988, you may call between the hours of 9:00 a.m. and 5:00 p.m., Monday-Friday. The new 1988 Pharmacy School catalog is now available for order.

Watch for Details, the MPhA working with the Mid Atlantic Food Dealers Association will soon offer a new electronic money order system which can make you money at competitive rates for other money order systems.

Do you have headaches? suffer from chronic depression? worry about the future of the profession? Then take two aspirin and tell your friends in Pharmacy to join with you in membership in the MPhA. The MPhA works fast-fast-fast to cure what ails you. Think about it.

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calendar

April 13 (Wed) AZO Seminar - Pharmacist Malpractice.

April 14 (Thur) MSHP Meeting - Mercy Hospital

April 19 (Tues) CECC Program with VA - Dermatology in Elderly.

May 12 (Thur) MSHP Meeting - Johns Hopkins

June 5 (Sun) CECC Seminar: Substance Abuse Among Pharmacy Staff

June 5-9 Annual ASHP Meeting - San Francisco

June 19-23 MPhA CONVENTION - SUN-SAND-CRABS BUSINESS-CE SEMINARS

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

Needed: Part-time pharmacist for consulting in long-term care facilities on the Eastern Shore. Clinical pharmacy and/or consulting experience preferred. Responsibilities include drug therapy review, committee meetings and pharmacy inspections.

Contact Lynda Oderda at 685-3272 for information.



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VOL. 64

April, 1988

NO. 4

Special Focus on Cancer

Advising Consumers on Fecal Blood Testing

—Thomas A. Gossel

—J. Richard Wuest

Cancer: Finding the Answers, Reducing the Risks

Cancer Treatment: What Lies Ahead

Alcohol—The Hidden Ingredient

—James R. Talley

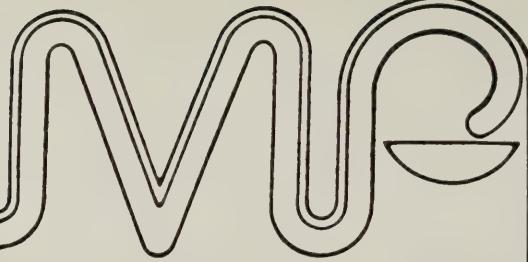
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APRIL, 1988

VOL. 64

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A VIEW ON POLITICS

Now that the 1988 General Assembly has ended, we have time to pause and reflect on the political process and how we as pharmacists can have a positive influence on the policy that impacts us financially and also affects our daily professional practice. There are a number of reasons why we could be much stronger politically than we already are:

1. Pharmacy practice enjoys a wide distribution throughout the state. There isn't a single district without a retail pharmacy or other pharmacy practice setting.
2. Pharmacists are the most highly respected professionals. This applies not only to the general public but we are also held in high regard by our elected representatives.
3. Almost every politician has developed a personal relationship with a pharmacist. Pharmacists individually have long supported their political candidates, with financial contributions and volunteer time.

We should capitalize on these strengths when we have our next opportunity for contact with an elected official, and not talk about the weather or their family. Take a minute to inform them of the dangers of physician dispensing and mail order pharmacy, the importance of freedom of choice when choosing health care providers, the inequity in balancing medical assistance budgets at the expense of pharmacy and indigent patients, the unfairness of higher copays in full service retail pharmacies as opposed to mail order pharmacies, or any other issue of concern.

Politicians listen when our lobbyist, or other representatives, testify but it doesn't have the impact a few minutes of one-on-one contact with their constituents can achieve. Make sure they are informed on both sides of the issues. Help your pharmacy association achieve our common goals. Become personally involved in the political process.

Lee Ahlstrom

President

Continuing Education

Advising Consumers on OTC Fecal Blood Testing Products

Objectives

At the conclusion of this lesson, participants will be able to:

1. define the meaning of the term "occult blood;"
2. elaborate on the etiology and prognosis of colorectal cancer;
3. identify specific factors that cause appearance of blood in the stool;
4. pick from a list of foods, those that could be consumed and others that should be avoided when testing for occult blood in the stool;
5. explain the proper use of OTC fecal occult blood testing products and outline how the products work; and
6. list specific points of consumer information to assure the tests are conducted properly.

When President Reagan was diagnosed as having colon polyps, fecal occult blood testing products suddenly became one of the more popular components of the OTC home health care marketplace.

While they can be used under physician supervision to help diagnose medical disorders that cause gastrointestinal (G.I.) bleeding, their most widely publicized use is as an aid in detecting colorectal cancer. A major goal of these products is to provide a convenient, simple-to-use, inexpensive, and accurate test that will detect cancerous lesions, early in their formation, in otherwise asymptomatic persons. Upon finding such lesions, the individual is urged to consult a physician for confirmation.

The directions and limitations for use of the various kits differ. Some of the newer products claim they are more convenient, but they all work on the same chemical principle. And they all provide accurate test results when used correctly.

What is Occult Blood?

The term "occult" refers to something that is unseen. In the area of clinical diagnosis, it relates to blood that is not visible to the unaided eye. Fecal occult blood is usually not seen because it is present in very small quantities.

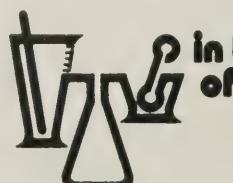
There are numerous factors that may cause blood in the feces (Table 1). Fecal blood may occur from normal physiological loss from the intestinal wall, ingestion of certain foods or drugs, pathogenic microorganisms and pathologic disease. Physicians routinely test the stool to confirm or refute suspicion of G.I. pathology.

One of the pathologic conditions that causes fecal blood loss is colorectal cancer. Cancerous lesions within the wall of the colon bleed even before they are well-developed. Therefore, testing the stool for occult blood is one method to detect them early. However, fecal occult blood detection is not diagnostic of cancer. The presence of blood in stool merely indicates that further testing is needed.

TABLE 1

Causes Of Blood In The Feces

| |
|--|
| Anal fissures |
| Bleeding scar from surgery |
| Diarrhea and possibly constipation |
| Diverticulitis |
| Drugs (e.g., aspirin, glucocorticoids) |
| Esophageal varices |
| Esophagitis |
| Gastrointestinal malignancy |
| Hemorrhoids |
| Hepatitis |
| Hiatal hernia |
| Long-distance running |
| Menstruation |
| Nose bleed |
| Peptic ulcer disease |
| Polyps |
| Proctitis |
| Ulcerative colitis |
| Uterine bleeding |



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Colorectal Cancer

Before President Reagan's surgery and follow-up examination, colorectal cancer was a form of neoplastic disease that was rarely discussed openly. The president's condition resulted in increased public awareness of the problem.

Lung and breast cancers routinely receive more press coverage. But colorectal cancer is the most common internal organ malignancy of both males and females. More than 160,000 Americans will develop it this year. More have reportedly died from colorectal cancer during the past 50 years than from any other form of cancer. It is exceeded only by skin cancer in incidence, and lung cancer in mortality. Colon cancer has a distinct advantage over lung and other organ cancers in that, with early detection, the diseased area of the colon can be removed and the remaining portion of the intestine resected. Alternatively, an ostomy procedure can be performed. After diverticulitis, colorectal cancer is the leading indication for a colostomy procedure.

In the U.S., the incidence of colorectal cancer is among the highest in the world. When persons from "low risk" countries (e.g., Japan, South Africa) immigrate to the U.S., their frequency of contracting the disorder increases to approximately that of native Americans. This strongly suggests that the cause is primarily environmental rather than genetic. Unfortunately, a specific factor has not been identified.

If detected and treated early, colorectal cancer has the highest five-year survival rate of all G.I. cancers. This is why fecal occult blood testing is so important.

More than one-half of all colorectal cancers reportedly begin in the rectum within a finger's-length of the anal sphincter. Seventy-five percent can be observed with a sigmoidoscope. Malignant areas further up in the colon can be seen with the longer colonoscope.

In theory, most colorectal cancers should be readily detected in routine physicals. However, digital examination and sigmoidoscopy/colonoscopy disclose less than one-half of the colorectal cancers that occur. Furthermore, in a study of patients with positive fecal occult

bleeding who had confirmed colon cancer, 36 percent of the lesions were not observed with a barium enema and x-ray examination. Guaiac testing for fecal occult blood has an overall predictive value for colorectal cancer of approximately 50 percent.

Colorectal tumors require a period of solid growth, often two or more years, before they are large enough to cause overt symptoms. Unfortunately for some patients, once symptoms appear, the prognosis is grave.

Colorectal cancer may have progressed to an advanced stage of development and still be relatively asymptomatic. Many people do not routinely visit a physician without symptoms of disease. The American Cancer Society estimates that only 12 percent of asymptomatic, but high-risk patients (Table 2) are ever tested for colorectal cancer. Survival from colorectal cancer will be maximized if treatment is initiated while the tumor is still localized.

Colorectal Cancer Related to Age. At age 40, the risk of colorectal cancer begins to increase. Before then, the occurrence is reported to be 5 per 100,000 population. During the next three decades, the risk increases exponentially. Eighty-seven percent of all colorectal cancers are detected in persons in their 50s. When no risk factors are present, regular testing should be undertaken at age 50. When any of the risk factors listed in Table 2 are present, the recommended age for testing is 40 or earlier.

It has been hypothesized that 95 percent of all colon cancers develop from neoplastic polyps. However, most colon polyps are not neoplastic. Twenty to 30 percent are ade-

nomatous (affecting the epithelial cells of the tissue). Ten percent of these are at risk for malignancy. There is a lengthy latency period, reported as long as 15 years between detection of polyps and progression to the neoplastic stage.

OTC Occult Blood Testing Products

In the late 1960s, the initial form of occult blood testing products was developed. Before then, patients collected stool samples in bottles and brought them to a physician or clinical laboratory to be tested with guaiac reagent solution.

Since then, simpler-to-use tests became standard fare, and they were quickly added as a standard component of professional diagnostic protocols. However, their use was restricted to physicians' offices and mass community screening programs.

In 1983, a product named Detec-test® was marketed specifically for home use. Others appeared shortly thereafter (Table 3). These newer tests became even more convenient to use, and eliminated the necessity of smearing fecal samples on cardboard slides. Therefore, they improved patient convenience and acceptance.

The tests rely on chemical reactions with guaiac. This consists of a group of different, but similar, compounds. One of them, alphaguaiaconic acid, is a colorless phenol that is oxidized by peroxidase to a blue-colored quinone. One product uses a slightly different process to yield a red-orange color. Hemoglobin contains the enzyme pseudoperoxidase which initiates the colorimetric change when it reacts with alpha-guaiaconic acid on the test product.

Consumers using the test should be advised not to consume either citrus fruits, or more than 250 mg of ascorbic acid, on the day prior to the test. Quantities less than 250 mg are absorbed into the blood, and will not influence test results. But higher amounts of ascorbic acid can remain in the stool, inhibiting peroxidase oxidation of guaiac. This will result in a false-negative response.

When counseling consumers on OTC fecal occult blood testing, it is important to inform them that it is not a specific indicator for the pres-

TABLE 2

Risk Factors For Colorectal Cancer

Family History

- Colorectal cancer or colon polyps
- Familial polyposis syndromes
- Juvenile polyps

Personal History

- Age 40 or over in asymptomatic persons
- Colorectal cancer or colon polyps
- Female genital or breast cancer
- History of adenoma of the colon
- Longstanding (7 or more years) ulcerative colitis involving the entire colon

TABLE 3**OTC Occult Fecal Blood Testing Products**

| Product (Mfr) | Test Product Controls | | Color if Test is Positive | Testing Procedure* |
|--|-----------------------|-----|---------------------------|---|
| | POS | NEG | | |
| ColoScreen Self-Test** (Helena Labs) | X | X | Red-orange | Paper pad; floated on water in toilet bowl after bowel movement |
| Detectest (C.B. Fleet) | X | | Blue | Fecal smear is streaked on surface of cardboard slide to which a developer is added |
| Early Detector (Warner-Lambert) | X | X | Blue | Paper pad; patted on anal area after bowel movement. Developer sprayed on paper pad |
| EZ-Detect Occult Blood Test (NMS Pharmaceuticals) | X | | Blue | Paper pad; placed in toilet bowl after bowel movement |
| Hemoccult II (Smith Kline Diag) | X | X | Blue | Fecal smear is streaked on surface of cardboard slide to which a developer is added |

*All tests depend on a colorimetric change of guaiac derivatives

**Manufacturer states that foods containing peroxidase are not a problem; chromagen present provides red-orange color in positive reactions

ence or absence of colorectal cancer. Instead, they test for the presence of blood in the stool. This differentiates them from most of the other OTC home testing products whose results are all-or-nothing in nature.

The accuracy of detection of occult blood using guaiac can be unpredictable. Test sensitivity is susceptible to influences such as the extent of hemoglobin degradation, amount of fecal drying, and presence of substances that trigger or inhibit oxidation of alpha-guaiaconic acid.

Cancerous colon lesions bleed intermittently. Therefore, it is necessary to test more than a single stool specimen. Tests should be conducted on three consecutive bowel movements. This may require from one to three or more days.

When undergoing testing, persons who use the products should understand that they must restrict their diet of red and raw meat, and vegetables that contain peroxidases (Table 4). Chicken, pork, bacon, ham, and fish are acceptable alternatives. They should adhere to a high roughage diet during the same period (Table 5). Roughage increases test accuracy since it encourages early small cancerous lesions to bleed.

An important but limiting factor is false-negative or false-positive test results. The former may give a false sense of security. The latter may trigger undue alarm.

Some interesting statistics have accumulated on the use and reliability of these testing products. One investigator found that for every 100,000 subjects over 40 years of age who have no overt symptoms of colorectal cancer, 3 percent (3,000) will show a positive fecal occult blood test. Of these, 150-300 will have a malignancy.

Another study involved over 2,300 persons who performed the tests. Five hundred thirty four (2.3 percent) had an initial positive reading. However, on retesting after diet modification, all results were negative, and none of the persons had colorectal cancer.

TABLE 5**Examples of High Fiber (Bulk) Food Items****Bread:**

Bran muffins, rye, whole wheat, raisin

Cereals:

Bran, grape-nuts, granola, oatmeal (not instant), puffed wheat, shredded wheat

Fruits:*

Apple, banana, cherry, peach, pear, plum, strawberry, tomato

Salad:

Cole slaw, lettuce, spinach, crouton

Snacks:

Jam, nuts, seeds, pepper, coconut, peanut butter, popcorn

Vegetables:*

Asparagus, cabbage, celery, corn, eggplant, lima bean, green bean, onion, pea, potato

*Should be eaten raw, or slightly cooked; too much cooking softens food and reduces its bulk

And in a study conducted in conjunction with a television station which featured a series of educational programs on colorectal cancer, stool guaiac slide kits were distributed to the community at a cost of \$1.00 each. A total of 8,711 kits were purchased; 3,832 were returned for developing. One hundred seven persons had at least one positive slide. Ninety of the persons with positive screens consulted a physician for further evaluation; seven new cases of colorectal cancer were discovered. Of these, five had lesions that were still localized. Four were asymptomatic prior to diagnosis.

Investigations have also been conducted to determine compliance with provided instructions. The results indicate an impressively high compliance rate of 80 percent. However, high compliance is rated in limited trials involving supervised groups of individuals rather than in home use without supervision.

While manufacturers' directions that accompany these products may seem easy to understand, they can be confusing to some persons. Every effort should be made to explain the product's directions and insure that purchasers will not have trouble fol-

TABLE 4**Examples Of Peroxidase-Rich Foods**

| | |
|-------------|-------------|
| Artichoke | Grapefruit |
| Broccoli | Horseradish |
| Cantaloupe | Mushroom |
| Carrot | Radish |
| Cauliflower | Turnip |
| Cucumber | |

TABLE 6**Patient Information**

- Do not collect fecal specimens if you have any bleeding disorder of the gastrointestinal or urogenital tract. Talk to your pharmacist.
- Do not use the kit if you are taking drugs, such as aspirin, phenylbutazone, indomethacin, steroids or reserpine, that are known to cause gastrointestinal bleeding, unless your doctor gives you specific instructions. They will interfere with the test. Stop using such drugs at least 48 hours before you begin the test. However, do not discontinue any prescribed medication or special diets without first consulting your doctor.
- Do not take high doses (over 250 mg) of vitamin C, laxatives, or use rectal ointments before performing the test.
- Flush the toilet and clean all chemicals from it before defecating, when performing the tests that require a stool specimen to be removed from the toilet bowl.
- Protect the testing kit from direct sunlight and other strong light sources, heat and open flames. Store it at room temperature, in a dry place. Do not use after the expiration date listed on the label.
- If you have trouble seeing or are color blind, ask someone else to help you read the results of the test.
- Complete all tests, for three consecutive bowel movements, even if the first two are negative.
- Develop all of the tests within the period specified on the package label and report any positive result to your doctor right away. Or, when appropriate, take the slides to your doctor or medical laboratory as soon as possible for analysis.

Table 6 is presented to help in patient counseling.

Fecal occult blood testing does not take the place of a physician's examination. A medical marketing consultant group has reported that most people who use home testing products do not have a personal physician. However, after conducting one or more tests and obtaining the results, they then seek a physician for assistance.

Consumers who ask for advice after a positive test result should be advised to consult their physician for further assessment. As stated earlier, a positive test result is not an absolute confirmation of cancer, but it indicates the need for further physical assessment.

Consumers with negative test results can be advised on the correct use of the test and the other warning signs of cancer (Table 7). If they note any change in bowel habits, abdominal or lower gut pain, or any of the other warning signs of cancer, they should contact their physician.

TABLE 7**Cancer's Seven Warning Signs***

- Change in bowel** or bladder habits
 - A sore that does not heal
 - Unusual bleeding or discharge
 - Thickening or lump in breast or elsewhere
 - Indigestion or difficulty in swallowing
 - Obvious change in wart or mole
 - Nagging cough or hoarseness
- * American Cancer Society
** Frequent episodes of diarrhea or constipation, blood on surface of stool or mixed with stool, episodes of abdominal cramping, abdominal pain associated with weight loss

lowing them. The instructions require the user to change his or her lifestyle and adhere to a strict behavioral protocol that may extend for five or more days.

Individuals who do not understand the potential severity of colorectal cancer, or who do not accept the fact that asymptomatic disease can still be lethal, may not comply with all testing directions. As with other health care concepts, more persons will comply when they understand why the test is important and how to use it. Information listed in

MEDICATION MEMO

Check (✓) the small box next to the questions you want to ask your doctor, pharmacist, or other health professional. Keep this Medication Memo as a reminder and write down the answers.



What is the name of the drug and what is it supposed to do?

Name of medicine _____

Purpose of this medicine _____



How and when do I take it—and for how long?

Other instructions _____



What foods, drinks, other medicines, or activities should I avoid while taking this drug?

Foods to avoid _____



Drinks to avoid _____



Medicines to avoid _____



Activities to avoid _____



Are there any side effects and what do I do if they occur?

Possible side effects _____

What to do if they occur? _____



Is there any written information available about the drug?

If you think you're having a heart attack, think out loud.



Chest discomfort that lasts longer than two minutes is nothing to fool around with.

Play it safe and ask someone to get you to a hospital emergency room—immediately.



American Heart Association
WE'RE FIGHTING FOR YOUR LIFE

22,000 Items. Now that's healthy!



You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

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Cancer: Finding the Answers, Reducing the Risks

The group of more than 100 different diseases called "cancer" are all caused by the uncontrolled growth and spread of abnormal cells.

Normal cells follow the genetic rules of growth and behavior as predetermined by the body's DNA (genetic material). Mysteriously, however, some cells turn abnormal and fail to follow these rules. They continue dividing and growing and eventually band together into *tumors*—masses of tissue. Tumors can be either *benign* or *malignant*.

Benign tumors are collections of cells that are only slightly abnormal and are not usually considered life-threatening.

Malignant tumors are cancerous. Untreated, they continue to grow, invading and *infiltrating* nearby tissues and organs (crowding out healthy cells and replacing them with cancer cells). Their most dangerous characteristic is that they metastasize (spread to other parts of the body through the bloodstream or lymph system). New malignant tumors take root in these new locations and grow and multiply.

The earlier a cancer is found, therefore, the easier it is to treat, and the better the patient's chance of beating the disease.

The Causes of Cancer: How Much Is Known?

Most cancers are believed to develop only after repeated contact with *carcinogens* (cancer-causing agents). Epidemiologists estimate that more than 80 percent of all cancers are caused by exposure to carcinogens. It is also possible to inherit a tendency to develop cancer. (See enclosure: Some Risk Factors and Their Associated Cancers).

At the cell level: Scientists believe many cancers are caused by a two-stage process involving *initiators* and *promoters*. Various agents called initiators somehow cause a cell to *mutate* (transform at the basic DNA level from its normal, healthy state). The mutation becomes carcinogenic, however, only when some other substance—a promoter—is added. If the promoter is never added, the mutated cell will remain latent (dormant) forever and never turn cancerous.

Tobacco: Cigarette smoking is the single most important cause of cancer deaths in the United States. Those who smoke two or more packs of cigarettes a day, for example, are 15 to 25 times more likely to die of cancer than nonsmokers.

"There is no single action an individual can take to reduce the risk of cancer more effectively than to quit smoking," the Surgeon General of the U.S., C. Everett Koop, M.D., Sc.D., has said.

It is well known that cigarette smoking causes the vast majority of lung cancers (85 percent in men, 75 percent in women), but it also increases the risk of developing several other types of cancer—those of the mouth, pharynx, larynx, esophagus, pancreas and bladder.

Smokeless tobacco: There is also strong evidence that the use of smokeless tobacco in the form of snuff or chewing tobacco causes cancer, particularly cancer of the oral cavity.

Involuntary smoking/“passive smoking”: Although some studies have failed to find an association, evidence continues to grow which indicates that people exposed to the cigarette smoke of others are being put at risk.

Sunlight: Exposure to the sun is the major cause of almost all of the more than 500,000 cases of non-melanoma skin cancer that develop each year in the U.S. Fortunately, most of these particular types of skin cancer are highly curable. Recent studies now show, however, that excess exposure to the sun is also related to malignant melanoma, a much more serious skin cancer that can spread to other parts of the body very quickly.

Radiation: Ionizing radiation or X-rays (invisible electromagnetic rays with a wavelength shorter than that of the visible and ultraviolet rays of the sun) can cause cancer or chromosomal damage, but the danger is in proportion to both the dose and duration of exposure.

Most of the information about the effects of radiation comes from studies of survivors of the atomic bombs dropped in Japan. These people have increased rates of several types of cancer—breast, thyroid, lung, stomach and acute leukemia.

The most common sources of ionizing radiation for medical reasons are diagnostic procedures and radiation therapy. In most cases, these X-rays can lead to life-saving or limb-saving medical treatment, and the possible benefits far outweigh the risks. Most modern medical equipment is now designed to deliver the lowest dose possible without sacrificing the beneficial effects.

Alcohol: Oral cancer and cancers of the larynx, throat, esophagus, liver and breast are more apt to develop among heavy drinkers of alcohol. The cancer risks of alcohol are increased even more in drinkers who are also cigarette smokers.

It has been shown that people who drink six or more *whiskey equivalents* (defined as the alcohol in 1 ounce of whiskey, which equals that in 12 ounces of beer or about 4 ounces of wine) a day may be at greater risk of developing *oral* cancer than smokers of 40 or more cigarettes a day. The risk also seems to be higher for those who drink beer or wine than for those who drink whiskey.

Occupational carcinogens: Many occupations expose workers to toxic fumes, gases, vapors, dust and airborne particles and potentially dangerous liquids and solids. These cancer-causing agents, called carcinogens, include asbestos, vinyl chloride, nickel, benzidine textile dyes, formaldehyde and arsenic. In addition to the immediate danger to the worker, the worker's family may also be in jeopardy. And exposed workers who smoke multiply their risk significantly.

Environmental pollution: Contrary to many people's impressions, air pollution is not a major cause of cancer.

"This is not to exonerate chemical pollutants, many of which are potent carcinogens," says Robert A. Weinberg, Ph.D., professor of biology at the Center for Cancer Research, Massachusetts Institute of Technology, Whitehead Institute for Biomedical Research, in Cambridge. "The evidence to date, however, shows that only a very small percentage of human cancer is traceable to environmental pollution or occupational exposure."

Another popular misperception is that "everything causes cancer." This false impression is based on a misunderstanding of the applicability of animal cancer tests to humans, according to Bruce N. Ames, Ph.D., professor of biochemistry at the University of California at Berkeley and the creator of the most widely used test-tube method of determining whether a chemical is carcinogenic.

Dr. Ames and his colleagues have devised a ranking system which shows that the carcinogenic hazards of low levels of many pesticides or polluted water are actually less than those of many natural substances, such as colas, beer, wine, raw mushrooms, brown mustard and peanut butter.

"There is increasing evidence that no human diet can be entirely free of mutagens or agents that can be carcinogenic in rodents," Dr. Ames says. "We need to identify the important causes of human cancer among the vast number of minimal risks."

Food and other nutritional factors: There is now good reason to suspect that dietary habits can contribute to the development of cancer, although the available information is far from clear-cut. The risk for colon, breast and uterine cancers increases for obese

people. A high-fat diet may be related to the development of breast, colon and prostate cancers. Salt-cured, smoked and nitrite-cured foods have been linked to cancers of the esophagus and stomach.

Heredity: "There is no doubt that certain families are cancer-prone," says Henry T. Lynch, M.D., director of the Hereditary Cancer Consultation Center, the first of its kind, at Creighton University Medical Center in Omaha, Neb. "When we find such families, we provide them with intensive education on the course of the cancer for which they're at risk."

"We strongly emphasize regular surveillance of all relatives who might inherit the cancer. Frequent checkups mean earlier diagnosis and a greater likelihood of a favorable outcome," he adds.

Dr. Lynch, who has studied hereditary cancer for more than 20 years and now maintains one of the world's largest registries of cancer-prone families, has found more than 100 well-established hereditary cancer syndromes such as retinoblastoma (an eye cancer that causes blindness) and familial polyps of the colon (which lead to colon cancer). Up to 10 percent of all cancers may be due to heredity, he says.

Viruses: Certain viruses are known to cause cancer in laboratory animals, and recent evidence shows that they may also be the cause of several types of cancer in humans. These types of cancers include certain *leukemias* (cancers of the blood system) and *lymphomas* (cancers of the lymph system), nasopharyngeal cancer, liver cancer and cervical cancer. In addition acquired immune deficiency syndrome (AIDS) can lead to certain lymphomas and leukemias and a type of cancer known as Kaposi's sarcoma.

Cancer Treatment—What Lies Ahead

Surgery and radiation therapy remain the mainstay of treatment for most cancers, particularly those discovered at an early stage.

But 12 tumors—representing about 10 percent of all cancers—are now considered curable in most patients with *chemotherapy*, treatment with anticancer drugs, either alone or in conjunction with the other two methods.

Chemotherapy is an area of treatment that is constantly changing as new drugs are developed and older drugs are used in new combinations.

Chemotherapeutic drugs interfere with the natural activity of cancer cells, either by sabotaging a specific phase of cell development directly or by sending confusing messages to the cells and causing them to destroy themselves.

These drugs are divided into six main groups: *alkalizing agents*, which interfere with cell division and react directly with DNA; *antimetabolites*, which hinder a cell's ability to reproduce exact copies of itself; *vinca alkaloids*, naturally occurring chemicals that stop a particular phase of cell division; *antibiotics*, natural substances that interfere with cell division and DNA synthesis; *hormones*, substances that occur naturally in the human body and send messages that either encourage or stop growth or activity in certain cells or organs; and a group of miscellaneous drugs, such as cisplatin (Platinol, Bristol-Myers)—a platinum-containing compound—that don't fit into any of the other categories.

Chemotherapy is most effective against cancers that have a large proportion of dividing cells; are small (either naturally or because the "bulk" of the tumor has been reduced by prior treatment with surgery or radiation therapy); or are *systemic* (affect the entire body).

For example, the antimetabolite cytosine arabinoside (Cytosar-U, Upjohn) is the drug of choice worldwide for patients with acute myelocytic leukemia—the most common acute leukemia of adults. Cytosar is also useful in acute lymphocytic leukemia—the number-one leukemia of children.

"Cytosar appears to kill cancer cells by entering the DNA of the cells and chemically blocking the duplication of cells undergoing DNA synthesis," says George L. Royer Jr., M.D., medical manager of clinical pharmacology and cancer chemotherapy research at The Upjohn Company in Kalamazoo, Mich. "The drug has been used in moderate doses, but recent research shows that patients can also tolerate 30 times the usual dose, offering the promise of extending survival."

Upjohn's other marketed anticancer drug, streptozocin (Zanosar), is also part of the treatment for a rare pancreatic cancer. And the company has a number of additional drugs in various stages of development.

"One agent we're enthusiastic about is tetraplatin—a platinum compound we're developing in collaboration with the National Cancer Institute," says Robert H. Earhart, M.D., Ph.D., clinical research manager of cancer and viral diseases research at Upjohn. "Studies in animal tumor models show that it is effective against tumors resistant to cisplatin. We hope it will work in tumors of the testes, ovaries and bladder where cisplatin has lost its effectiveness."

Hormone therapy: Two types of steroid hormones are used in therapy—sex hormones and glucocorticoids. The former act on a very specific group of tissues and are useful in treating some breast, prostate, uterine and kidney cancers. Glucocorticoid hormones act on a wide variety of tissues and organs are used to treat Hodgkin's disease; lymphocytic and histiocytic lymphomas; lymphoblastic, lymphocytic and acute myelogenous leukemias; and multiple myeloma.

Bolstering the Patient's Own Immune System

A new and exciting, although still largely experimental, method of fighting cancer—one that beefs up the body's own disease-fighting immune system—has recently been introduced. This class of compounds, called *biological response modifiers*, includes interferon; interleukin-2; tumor necrosis factor; interferon-inducers; monoclonal antibodies; differentiation agents; adoptive cellular therapy with lymphokine-activated killer cells and interferon-activated macrophages; and bropirimine.

"Many of these substances are manufactured by the body's own cells for the specific purpose of controlling the growth of other cells and are responsible for the orderly development of organs in the body," says Emil J. Freireich, M.D., D.Sc., head of the department of developmental therapeutics at the University of Texas System Cancer Center, M.D. Anderson Hospital in Houston.

"The technology for growing human cells in test tubes has advanced to the point where many different types of cells can be grown in tissue culture and can be induced to manufacture biological response modifiers. We have the potential for making a whole new generation of drugs that operate like insulin for the control of

insulin-dependent diabetes or like cortisone for replacing the function of the adrenal glands," he says.

Alpha interferon (Roferon A, Hoffmann-LaRoche; Intron A, Schering-Plough), the first biological treatment to be approved for use outside of experimental trials, is now the treatment of choice for hairy-cell leukemia, a rare disease that once was almost invariably fatal. It also shows promise for patients with multiple myeloma, the "epidemic" form of Kaposi's sarcoma that accompanies acquired immune deficiency syndrome (AIDS) and kidney cancer.

Steven A. Rosenberg, M.D., Ph.D., chief of the surgery branch of the National Cancer Institute, recently reported that patients with certain types of far-advanced cancer had responded to a treatment called *adoptive immunotherapy*, which uses human immune cells activated by *interleukin-2* (IL-2), a growth factor. Dr. Rosenberg found that a group of human lymphocytes, normally found circulating in the bloodstream, could be activated to kill tumor cells if exposed to IL-2.

Bropirimine is the most promising of a group of substances called pyrimidinones that stimulate the body to produce interferon.

"Bropirimine may be a useful adjunct to present cancer treatments by helping the body rid itself of resistant cells that remain after standard treatment," says Wendell Wierenga, Ph.D., director of cancer and viral diseases research at Upjohn. "The substance appears to stimulate killer and scavenger white blood cells as well as those that secrete interferon and interleukins."

Tumor necrosis factor (TNF) is a natural body protein that has been shown to cause tumors to die (necrose) in experimental animals. Genetic engineering companies can now produce TNF in the laboratory, but research in human cancers is just beginning.

Cutting Off a Tumor's Blood Supply

It is well known that tumors have the ability to induce the formation of a thicket of new capillary blood vessels that eventually cut off the blood supply to the surrounding healthy tissues and organs, starving them of needed oxygen and nutrients. This capacity is called *angiogenesis*.

"As we begin to understand more about the biological mechanisms of angiogenesis, it may be possible to develop therapeutic approaches for cancer and other angiogenic diseases," says M. Judah Folkman, M.D., professor of pediatric surgery at Harvard Medical School and director of the surgical research laboratory at Children's Hospital in Boston. Dr. Folkman has been studying the process for nearly 20 years.

Monoclonal Antibodies: Getting Specific

Monoclonal antibodies are very specific *antibodies* (proteins formed by the immune system to react with foreign proteins or other large molecules) developed in the laboratory less than 10 years ago with genetic engineering and cloning techniques.

Although monoclonal antibodies are already being successfully used in diagnosis, their greatest potential lies in treatment. It is hoped that monoclonals will one day be employed to destroy or damage cancer cells selectively, sparing healthy tissue the damage typically wrought by chemotherapy.

Improving Quality of Life

Now that medical advances have extended the survival of cancer patients, there is a new awareness of the importance of improving the quality of life for both the cancer patient and the family. Their reactions to the disease, sexual concerns, employment and insurance questions and need for psychosocial support have all emerged as important areas of research and clinical care.

Consultation liaison psychiatry is devoted to the treatment of patients with physical illnesses or complaints who also have psychological problems.

"The goal is to integrate the biological, psychological and social needs of the patient," says Robert O. Pasnau, M.D., former president of the American Psychiatric Association and professor in the department of psychiatry and biobehavioral sciences at the University of California at Los Angeles School of Medicine. "The techniques used include biofeedback, stress reduction, hypnotherapy, behavior modification, drug therapy and psychotherapy with an important focus on the family."

A wide variety of medications is available to treat the complications that often accompany cancer. For example, alprazolam (Xanax) has been used successfully to alleviate anxiety, which triazolam (Halcion) counteracts insomnia. Steroids can help bring back appetite and fight cachexia (the loss of weight and "wasting away" that is common in the later stages of cancer); steroid preparations often restore the patients' sense of well-being. Various antibiotics are available to deal with infections that occur as a result of patients' lowered immunity and threaten the patients' lives.

Treating pain: Pain is one of the most feared consequences of cancer. According to World Health Organization experts, over half of cancer patients suffer needlessly. This is true of patients in developed countries as well as those in Third World nations.

Experience shows that patients can be treated effectively with an approach that combines drug therapy, neurosurgical and anesthetic methods, relaxation training and other behavioral approaches and supportive care. To allay cancer pain, drug doses should be varied according to an individual patient's needs.

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A Guide To Proper Nutrition For The Patient Undergoing Cancer Therapy. This booklet has been prepared to help cancer therapy patients recognize, understand, and cope with obstacles to good nutrition. It also discusses nutritional supplements such as Sustacal® as a way to improve nutrition. *Available in Spanish. *Distributed through medical professionals only. *Mead Johnson & Company*

A Lifetime Of Emotion Wrapped Up In One Word: Cancer. As part of the Pfizer Health Care Series, this one-page information sheet discusses the importance of early cancer diagnosis, current cancer research, and the patient's role as part of the health care team. *Pfizer Pharmaceuticals*

Feeling Good: Nutrition Planning to Improve Your Cancer Therapy. This guide provides sensible tips to the cancer patient who may be experiencing difficulty with diet and nutrition. Specific problems are addressed and possible solutions included. In addition, a brief discussion on cancer and its treatment regimes is provided. *Mead Johnson & Company*

Mouth Care Instructions For Chemotherapy And Radiation Therapy Patients. Written for patients who have undergone chemotherapy affecting the mouth, teeth, or gums, this booklet provides special instructions for mouth care. *Distributed to health care professionals. *Ross Laboratories*.

Nuclear Medicine: The Benefits And The Risks. The history of nuclear medicine, beginning with the first x-rays, is presented in this 24-page booklet. An explanation of the more common applications, such as in bone scanning, heart disease, and radio-iodine treatment, are discussed as are the safety and benefits of radiation therapy. *Hoffmann-La Roche Inc.*

Nutrition: An Ally in Cancer Therapy. The problems that cancer patients may have with eating are examined in this booklet. Copying mechanisms, ways to ensure proper nutrition, and the use of nutritional supplements are also discussed. *Distributed to health care professionals. *Ross Laboratories*

Your Treatment For Cancer. The How And Why Of Chemotherapy. This 12-page booklet explains chemotherapy in terms of how it works, how and why it may cause side effects, and what can be done to prevent them. *Lederle Laboratories*

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Institutional Forum

Alcohol: The Hidden Ingredient in Most Liquid Dosage Forms of Cough, Cold, & Allergy Medications

James R. Talley, M.S., and Monica Holiday, R.Ph.

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Northeast Louisiana University
Monroe, Louisiana

Introduction

A large number of liquid medications used in the treatment of coughs, colds, and allergies contain alcohol. The alcohol in these products serve a useful purpose because alcohol is an excellent solvent for keeping other ingredients dissolved in the liquid dosage form. The amount of alcohol used as a solvent may depend on the solubility of these active ingredients. Although alcohol is contained in many of these products primarily as a vehicle, its sedative activity may also qualify it as a drug.¹ Thus, in certain circumstances and disease states, alcohol may result in serious consequences.

Alcohol Use in Children

Alcohol poses special problems for children. Even small amounts of alcohol may adversely affect a child's central nervous system. This may be manifested as decreased reaction time, muscular incoordination, and behavioral changes. Alcohol may also affect the action of other drugs in children. Alcohol may result in the development of hypoglycemia in both children and adults. This is because as alcohol is metabolized, the body's glucose production is reduced. Children use up glucose stores rapidly and therefore are particularly susceptible to hypoglycemia due to alcohol. It has been recommended that products which contain greater than 10 percent alcohol should only be administered to children under 6 years of age with a physician's supervision.

Alcohol-Drug Interactions

Alcohol is a sedative and therefore may interact with other drugs which have sedative effects. Patients should be aware of the serious complications that may occur when drugs and alcohol are combined. Alcohol in combination with drugs has been reported to account for approximately 20% of the total number of drug-related deaths per year.^{2,3} A number of patients are un-

aware of the serious complications that may occur when alcohol is taken with certain drugs.⁴ Some patients do not realize they are ingesting alcohol because of its use as a diluent or vehicle in numerous prescription and nonprescription products.¹

Drug-alcohol interactions may cause alterations in the pharmacologic effect of either entity.⁵ The probability of a clinically significant interaction and severity of the interaction depends on a number of factors: the patient's size, sex, and age; ability to metabolize the drug and the alcohol; general state of health; and the frequency and amounts consumed. Ingestion of ethanol may increase drug absorption by enhancing gastric solubility and increasing gastrointestinal blood flow.⁶ It has been reported that beverages containing greater than 6% ethanol speed gastric emptying.⁷ Because the major site for absorption of alcohol and a number drugs is the small intestine rather than the stomach, drug absorption is accelerated. Alcohol concentrations greater than 20% may result in delayed drug absorption or reduced drug bioavailability by inducing gastric irritation and provoking pyloric spasm. In conjunction, drugs that affect gastric motility may increase or decrease the rate of alcohol absorption. For example, metoclopramide, cholinergic agents, and chlorpromazine all speed alcohol absorption and may result in unexpected inebriation.⁷

Mild alcohol intoxication may impair the metabolism of other drugs by competing for the same enzyme system.⁸ Alcohol is metabolized in the liver (primarily by alcohol dehydrogenase and aldehyde dehydrogenase) to form carbon dioxide and water.⁹ Some alcohol is metabolized by the hepatic microsomal mixed function (MFO) system which also metabolizes numerous drugs. Therefore, excessive chronic alcohol consumption may result in seriously impaired liver function due to alcoholic hepatitis with eventual alcoholic cirrhosis

in approximately 10% to 30% of chronic alcoholics.¹⁰ In these patients, certain drugs taken concurrently will accumulate in the body and increase the possibility of serious side effects. It is important to realize that chronic or even moderate use of alcohol may stimulate the MFO system and cause other drugs to be metabolized faster. Alcohol may shorten the half-lives of certain drugs and lower plasma concentrations to subtherapeutic levels.⁸

Patients taking disulfiram (Antabuse) should be especially cautious about using medications that contain alcohol. Disulfiram is used to treat alcohol abuse by promoting abstinence.⁵ This interaction differs from most other drug and alcohol combinations because symptoms may occur with a only a small amount of alcohol in the bloodstream. This interaction, referred to as the "disulfiram reaction" includes symptoms of flushing of the face, headache, respiratory difficulty, nausea, copious vomiting, sweating, chest pain, fall in blood pressure, orthostatic fainting, vertigo, uneasiness, confusion, sometimes convulsions, and a risk of shock.¹¹ Because alcohol is so prevalent in liquid medications, pharmacists should advise patients in regard to alcohol content.

Drugs that affect the CNS are the most likely to be abused and cause serious interactions when taken with alcohol. Because narcotics have a CNS depressant effect, problems occur when patients consider codeine containing nonprescription analgesics and cough syrups as innocuous medications. When combined with alcohol, these medications may lead to severe intoxication. Severe depression of the respiratory center may occur when neuroleptics (i.e., chlorpromazine, thioridazine) and ingested with alcohol.

Alcohol combined with other sedatives or hypnotics has an additive CNS depressant activity with symptoms of vasodilation, rapid heartbeat, and headache; all of which are serious complications for patients with cardiovascular disease.⁴ Alcohol and diazepam have an additive effect on the CNS which is detrimental to psychomotor skills.¹² Enhanced sedation and psychomotor impairment may occur with alcohol and certain tricyclic antidepressants, especially during the first week of therapy.^{9,12} It is important to realize that an interaction between benzodiazepines and alcohol may occur up to ten hours after the drug is taken.³ Salicylates and nonsteroidal anti-inflammatory analgesics may cause gastrointestinal bleeding and gastric irritation, and when combined with alcohol these toxic effects may be enhanced.⁹

Several antimicrobial drugs (cefamandole, moxalactam, chloramphenicol, griseofulvin, isoniazid, metronidazole, and quinacrine) may inhibit aldehyde dehydrogenase. This may result in a mild but unpleasant disulfiram-type interaction with alcohol.^{4,9} Symptoms caused by combinations of these antimicrobial agents and alcohol include: nausea, vomiting, headache, hypotension, and peripheral vasodilation.

Alcohol has some vasodilation effects and when combined with certain antihypertensives (reserpine, methyldopa, guanethidine, and ganglionic blockers) orthostatic hypotension may be enhanced and result in a severe reduction in blood pressure.^{5,9,12} The hypotensive side effect of phenothiazines may also be exacerbated by alcohol.⁵ Beta adrenergic blockers (propranolol) may interact with alcohol and mask tachycardia and tremor which are symptoms of alcoholic hypoglycemia.

Alcohol containing products may pose special problems with diabetic patients because alcohol will contribute additional calories to the diabetic's restricted diet. The hypoglycemic action of insulin may be augmented by alcohol, inhibited gluconeogenesis. Chronic alcohol consumption may result in increased metabolism of the sulfonylureas which results in decreased drug effectiveness.⁹ Patients taking chlorpropamide or tolbutamide and ingesting alcohol may experience a disulfiram-like reaction, characterized by facial flushing.⁹ As a final note, anticoagulants (warfarin) may interact with alcohol and result in fluctuations in prothrombin time.

Conclusions

Because alcohol is so prevalent in these types of medications, pharmacists should advise patients in regard to alcohol content. It is professionally prudent to make the patient aware of any possible complications. As pharmacists, it is our professional obligation to warn patients of possible occurrence of drug and alcohol interactions. This is necessary not only for the well-being of the patient, but also because of our legal obligations to be knowledgeable about drug interactions. The occurrence of detrimental interactions between alcohol and drugs should be of paramount importance to all pharmacists.

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TABLE 1
Alcohol Containing Cough, Cold, & Allergy Medications

| NAME OF PRODUCT | | COMPANY | ALCOHOL % |
|----------------------------|--------------------------|-------------|-----------|
| BRONCHODILATORS | | | |
| Rx | Accurbron Elixir | Merrell Dow | 7.50 |
| Rx | Choledyl Elixir | Parke-Davis | 20.00 |
| Rx | Dilor Elixir | Savage | 18.00 |
| Rx | Lufyllin Elixir | Wallace | 20.00 |
| Rx | Theon Syrup | Bock | 1.00 |
| Rx | Theostat 80 Syrup | Laser | 1.00 |
| ANTIHISTAMINES | | | |
| otc | Actidil Syrup | B-W | 4.00 |
| otc | Aller-Chlor Syrup | Rugby | 7.00 |
| otc | Belix Elixir | Halsey | 14.00 |
| Rx | Benadryl Elixir | Parke-Davis | 14.00 |
| otc | Benadryl Elixir | Parke-Davis | 14.00 |
| otc | Benylin Cough Syrup | Parke-Davis | 5.00 |
| otc | Bydramine Cough Syrup | Major | 5.00 |
| otc | Chlor-Trimeton Syrup | Schering | 7.00 |
| Rx | Diahist Elixir | Century | 14.00 |
| otc | Dimetane Elixir | Robins | 3.00 |
| otc | Diphen Cough Syrup | My-K Labs | 5.00 |
| otc | Hydramine Elixir | Goldline | 14.00 |
| Rx | Myidil Syrup | My-K Labs | 4.00 |
| otc | Nordryl Cough Syrup | Vortech | 5.00 |
| Rx | Periactin Syrup | MSD | 5.00 |
| Rx | Phenergan Plain Syrup | Wyeth | 7.00 |
| Rx | Phenergan Syrup Fortis | Wyeth | 1.50 |
| otc | Phenetron Syrup | Lannett | 7.00 |
| Rx | Polaramine Syrup | Schering | 6.00 |
| Rx | Poly-Histine Elixir | Bock | 4.00 |
| Rx | Prothazine Plain Syrup | Vortech | 7.00 |
| Rx | Tavist Syrup | Sandoz | 5.50 |
| Rx | Temaril Syrup | Herbert | 5.70 |
| Rx | Tusstat Syrup | Century | 5.00 |
| Rx | Valdrene Syrup | Vale | 5.00 |
| ANTITUSSIVES | | | |
| otc | Beldin Syrup | Halsey | 5.00 |
| otc | Benylin Cough Syrup | Parke-Davis | 5.00 |
| otc | Benylin DM Syrup | Parke-Davis | 5.00 |
| otc | Bydramine Syrup | Major | 5.00 |
| otc | Cremacoat 1 Syrup | Vicks | 10.00 |
| otc | DM Cough Syrup | My-K Labs | 5.00 |
| otc | Diphen Cough Syrup | My-K Labs | 5.00 |
| otc | Nordryl Cough Syrup | Vortech | 5.00 |
| otc | Pertussin Syrup | Canaan | 9.50 |
| Rx | Tusstat Syrup | Century | 5.00 |
| Rx | Valdrene Syrup | Vale | 5.00 |
| EXPECTORANTS | | | |
| otc | Anti-Tuss Syrup | Century | 3.50 |
| otc | Cherralex Plain Liquid | Barre | 3.00 |
| otc | Colrex Expectorant Syrup | Reid-Rowell | 4.70 |
| otc | Cremacoat 2 Syrup | Vicks | 10.00 |
| otc | GG-Cen Syrup | Central | 10.00 |
| otc | Genatuss Syrup | Goldline | 3.50 |
| otc | Glyate Syrup | Geneva | 3.50 |
| otc | Halotussin Syrup | Halsey | 3.50 |
| otc | Malotuss Syrup | Mallard | 3.50 |
| otc | Mytussin Syrup | My-K Labs | 3.50 |
| otc | Nortussin Syrup | Vortech | 3.50 |
| Rx | Organidin Elixir | Wallace | 21.75 |
| otc | Rasp Cough Syrup | Commerce | 2.00 |
| otc | Robafen Syrup | Major | 3.50 |
| otc | Robitussin Syrup | Robins | 3.50 |
| otc | Scot-tussin Syrup | Scot-Tussin | 3.50 |
| ANTIASTHMATIC COMBINATIONS | | | |
| Rx | Asbron G Elixir | Sandoz | 15.00 |
| Rx | Brondecon Elixir | Parke-Davis | 20.00 |
| Rx | Brondelate Elixir | various | 20.00 |
| otc | Bronkolixir Elixir | Winthrop | 19.00 |
| C-5 | Co-Xan Syrup | Central | 10.00 |
| Rx | Elixophyllin KI Elixir | Forest | 10.00 |
| Rx | Guiaphed Elixir | various | 19.00 |
| Rx | Hydrophed D.F. Syrup | Rugby | 5.00 |
| Rx | Isogen Compound Elixir | Rugby | 19.00 |

TABLE 1
Continued

| NAME OF PRODUCT | | COMPANY | ALCOHOL % |
|--|------------------------------------|----------------|-----------|
| Rx | Isolate Compound Elixir | various | 19.00 |
| Rx | Lufyllin-EPG Elixir | Wallace | 5.50 |
| Rx | Lufyllin-GG Elixir | Wallace | 17.00 |
| Rx | Marax D.F. Syrup | Roerig | 5.00 |
| Rx | Mudrane GG Elixir | Poythress | 20.00 |
| Rx | Quibron Plus Elixir | Bristol-Myers | 15.00 |
| Rx | Synophylate-GG Syrup | Central | 10.00 |
| otc | Tedral Elixir | Parke-Davis | 15.00 |
| Rx | Theo-Organidin Elixir | Wallace | 15.00 |
| Rx | Theo-R-Gen Elixir | Goldline | 15.00 |
| Rx | Theophylline KI Elixir | various | 10.00 |
| DECONGESTANT & ANTIHISTAMINE COMBINATIONS | | | |
| otc | Alamine Liquid | Vortech | 5.00 |
| otc | Benylin Decongestant Liquid | Parke-Davis | 5.00 |
| otc | Bromatap Elixir | Goldline | 2.30 |
| Rx | Bromophen Elixir | Rugby | 2.30 |
| otc | Demazin Syrup | Schering | 7.50 |
| otc | Dimetane Decongestant Elixir | Robins | 2.30 |
| otc | Dimetapp Elixir | Robins | 2.30 |
| otc | Duphrene Syrup | Vale | 5.00 |
| Rx | E-Tapp Elixir | Edwards | 2.30 |
| otc | Genatap Elixir | Goldline | 2.30 |
| otc | Hista-Vadrin Syrup | Scherer | 2.00 |
| Rx | Histor-D Syrup | Hauck | 2.00 |
| Rx | Midatapp Elixir | Vanguard | 2.30 |
| otc | Myhistine Elixir | My-K Labs | 5.00 |
| otc | Myphetapp Elixir | My-K Labs | 2.30 |
| Rx | Normatane Elixir | Vortech | 2.30 |
| otc | Novahistine Elixir | Lakeside | 5.00 |
| Rx | Phenergan VC Syrup | Wyeth | 7.00 |
| Rx | Pherazine VC Syrup | Halsey | 7.00 |
| Rx | Poly-Histine-D Elixir | Bock | 4.00 |
| Rx | Prometh VC Plain Liquid | Goldline | 7.00 |
| Rx | Promethazine VC Syrup | various | 7.00 |
| otc | Ru-Tuss Liquid | Boots | 5.00 |
| otc | Trind Liquid | Mead Johnson | 5.00 |
| Rx | Tussanil Plain Syrup | Misemer | 5.00 |
| Rx | Veltap Elixir | Lannett | 3.00 |
| ANTITUSSIVE COMBINATIONS | | | |
| C-5 | Actagen-C Cough Syrup | Goldline | 4.30 |
| C-5 | Actifed w/Codeine Cough Syrup | B-W | 4.30 |
| C-5 | Alamine-C Liquid | Vortech | 5.00 |
| otc | All-Nite Cold Formula Liquid | Major | 25.00 |
| C-5 | Allerfrin w/Codeine Syrup | Rugby | 4.30 |
| C-5 | Ambenyl Syrup | Forest | 5.00 |
| C-5 | Bromanate DC Cough Syrup | various | 0.95 |
| C-5 | Bromanyl Syrup | various | 5.00 |
| C-5 | Bromotuss w/Codeine Syrup | Rugby | 5.00 |
| C-5 | Bromphen DC w/Codeine Cough Syrup | various | 0.95 |
| Rx | Carbodec DM Syrup | Rugby | 0.60 |
| Rx | Cardec DM Syrup | various | 0.60 |
| otc | Cerose-DM Liquid | Wyeth | 2.40 |
| otc | Cheracol Plus Liquid | UpJohn | 8.00 |
| otc | CoTylenol Cold Medication Liquid | McNeil | 7.50 |
| otc | Codimal DM Syrup | Central | 4.00 |
| C-5 | Colrex Compound Elixir | Reid-Rowell | 9.50 |
| otc | Colrex Cough Syrup | Reid-Rowell | 4.50 |
| otc | Comtrex Liquid | Bristol-Myers | 20.00 |
| otc | Contact Severe Cold Formula Liquid | SKF | 25.00 |
| C-3 | Detussin Liquid | various | 5.00 |
| C-5 | Dihistine DH Elixir | Goldline | 5.00 |
| C-5 | Dimetane-DC Cough Syrup | Robins | 0.95 |
| Rx | Dimetane-DX Cough Syrup | Robins | 0.95 |
| otc | Formula 44 Cough Mixture | Vicks | 10.00 |
| otc | Genite Liquid | Goldline | 25.00 |
| otc | Halls Mentho-Lyptus Decongestant | Warner-Lambert | 22.00 |
| C-5 | Histadyl E.C. Syrup | Lilly | 5.00 |
| C-5 | Mallergan-VC w/Codeine Syrup | Mallard | 7.00 |
| C-5 | Midahist DH Elixir | Vanguard | 5.00 |
| otc | My-K Formula 77 Liquid | My-K Labs | 10.00 |
| C-5 | Mybanil Syrup | My-K Labs | 5.00 |

TABLE 1
Continued

| | NAME OF PRODUCT | COMPANY | ALCOHOL % |
|--------------------------------|---------------------------------------|----------------------|-----------|
| C-3 | Mycotussin Liquid | My-K Labs | 5.00 |
| C-5 | Myhistine DH Liquid | My-K Labs | 5.00 |
| C-5 | Myphetane DC Cough Syrup | My-K Labs various | 0.95 |
| Rx | Myphetane DX Syrup | Vortech | 0.95 |
| C-5 | Normataine DC Syrup | Lakeside | 5.00 |
| otc | Novahistine Cough & Cold Formula | Lakeside | 5.00 |
| C-5 | Novahistine DH Liquid | Vicks | 25.00 |
| otc | NyQuil Nighttime Cold Medicine | Rugby | 25.00 |
| otc | Nytyme Cold Medicine Liquid | Canaan | 9.50 |
| otc | Pertussin AM Liquid | Canaan | 25.00 |
| otc | Pertussin PM Liquid | Major | 7.00 |
| C-5 | Phenameth VC w/Codeine Syrup | Major | 7.00 |
| C-5 | Phenameth w/Codeine Syrup | Wyeth | 7.00 |
| C-5 | Phenergan VC w/Codeine Syrup | Wyeth | 7.00 |
| C-5 | Phenergan w/Codeine Syrup | Wyeth | 7.00 |
| Rx | Phenergan w/Dextromethorphan Syrup | Halsey | 7.00 |
| C-5 | Pherazine VC w/Codeine Syrup | Barre | 7.00 |
| C-5 | Prometh VC w/Codeine Syrup | Barre | 7.00 |
| C-5 | Prometh w/Codeine Syrup | Barre | 7.00 |
| Rx | Prometh w/Dextromethorphan Syrup | Barre | 7.00 |
| C-5 | Promethazine HCl w/Codeine Syrup | various | 7.00 |
| C-3 | Promist HD Liquid | Russ | 5.00 |
| Rx | Prothazine Pediatric Liquid | Vortech | 7.00 |
| C-5 | Prothazine-DC Liquid | Vortech | 7.00 |
| Rx | Pseudo-Car DM Syrup | Geneva | 0.60 |
| otc | Quiet Night Liquid | My-K Labs | 25.00 |
| otc | Robitussin Night Relief Colds Formula | Robbins | 25.00 |
| Rx | Rondec-DM Syrup | Ross | 0.60 |
| C-3 | Ru-Tuss w/Hydrocodone Liquid | Boots | 5.00 |
| C-5 | Triacin C Cough Syrup | various | 4.30 |
| Rx | Tricoline Expectorant | Major | 0.60 |
| C-5 | Trifed-C Cough Syrup | Geneva | 4.30 |
| otc | Trind DM Liquid | Mead Johnson | 5.00 |
| Rx | Tusquelin Syrup | Circle | 5.00 |
| Rx | Tuss-Ornade Liquid | SKF | 5.00 |
| Rx | Tussadon Liquid | Rugby | 5.00 |
| Rx | Tussafed Syrup | Everett | 0.60 |
| C-3 | Tussanil DH Syrup | Misemer | 5.00 |
| C-3 | Tussend Liquid | Merrell Dow | 5.00 |
| C-3 | Tussionex Suspension | Pennwalt | 0.59 |
| EXPECTORANT COMBINATIONS | | | |
| Rx | Bromphen Expectorant | various | 3.50 |
| Rx | Entex Liquid | Norwich-Eaton | 5.00 |
| otc | Health & Chest Liquid | Vicks | 5.00 |
| Rx | Histalet X Syrup | Reid-Rowell | 15.00 |
| otc | Myminic Expectorant | My-K Labs | 5.00 |
| otc | Naldecon-Ex Pediatric Drops | Bristol | 0.60 |
| Rx | Norisodrine w/Calcium Iodide Syrup | Abbott | 6.00 |
| Rx | Normatane Expectorant | Vortech | 3.50 |
| Rx | Polaramine Expectorant | Schering | 7.20 |
| otc | Robitussin-PE Syrup | Robins | 1.40 |
| otc | Rymed Liquid | Edwards | 5.00 |
| otc | Triaminic Expectorant | Sandoz | 5.00 |
| otc | Triphenyl Expectorant | Rugby | 5.00 |
| ANTITUSSIVES with EXPECTORANTS | | | |
| otc | Benylin DME Liquid | Parke-Davis | 5.00 |
| C-5 | Calcidrine Syrup | Abbott | 6.00 |
| otc | Cheracol D Cough Liquid | UpJohn | 4.75 |
| C-5 | Cheracol Syrup | UpJohn | 4.75 |
| C-5 | Cheralin Syrup | Lannett | 3.00 |
| otc | Codistan No. 1 Syrup | Vortech | 1.40 |
| c-ii | Dilauidid Cough Syrup | Knoll | 5.00 |
| otc | Genatuss DM Expectorant | Goldline | 1.40 |
| otc | Glycotuss-dM Syrup | Vale | 4.75 |
| C-5 | Guiamid A.C. Liquid | Vangard | 3.50 |
| otc | Guiamid DM Liquid | Vangard | 1.40 |
| C-5 | Guiatuss A.C. Syrup | various | 3.50 |
| otc | Guiatuss-DM Syrup | various | 1.40 |
| C-5 | Guiatussin w/Codeine Expectorant | Rugby | 3.50 |
| C-3 | Hycotuss Expectorant Liquid | DuPont | 10.00 |
| C-5 | Mytussin AC Expectorant | My-K Labs | 3.50 |

TABLE 1
Continued

| | NAME OF PRODUCT | COMPANY | ALCOHOL % |
|--|--|-------------|-----------|
| otc | Mytussin DM Expectorant | My-K Labs | 1.40 |
| C-5 | Nortussin w/Codeine Liquid | Vortech | 3.50 |
| otc | Pertussin CS Liquid | Canaan | 8.50 |
| C-5 | Prunicodeine Liquid | Lilly | 25.00 |
| C-5 | Robitussin A-C Syrup | Robins | 3.50 |
| otc | Robitussin-DM Syrup | Robins | 1.40 |
| otc | Terphan Elixir | Vale | 40.00 |
| C-5 | Terpin Hydrate and Codeine Elixir | various | 40.00 |
| otc | Terpin Hydrate w/Dextromethorphan HBr | various | 43.00 |
| otc | Terpin-Dex Elixir | Halsey | 41.50 |
| C-5 | Tolu-Sed Cough Syrup | Scherer | 10.00 |
| otc | Tolu-Sed DM Liquid | Scherer | 10.00 |
| ANTITUSSIVE & EXPECTORANT COMBINATIONS | | | |
| C-5 | Alamine Expectorant | Vortech | 7.50 |
| otc | Ambenyl-D Decongestant Cough Formula | Forest | 9.50 |
| C-5 | C-Tussin Expectorant | Century | 7.50 |
| C-3 | Citra Forte Syrup | Boyle | 2.00 |
| C-5 | Codafed Expectorant | Hauck | 7.50 |
| otc | Coricidin Cough Syrup | Schering | 0.50 |
| otc | DayCare Expectorant Liquid | Vicks | 10.00 |
| C-3 | Detussin Expectorant | various | 12.50 |
| C-5 | Dihistine Expectorant | various | 7.50 |
| otc | Dimacol Liquid | Robins | 4.75 |
| otc | Formula 44D Decongestant Cough Mixture | Vicks | 10.00 |
| otc | Formula 44M Liquid | Vicks | 20.00 |
| C-5 | GuiaTuss DAC Syrup | various | 1.40 |
| C-5 | Isoclor Expectorant | Fisons | 5.00 |
| otc | My-K Formula 77D Liquid | My-K Labs | 10.00 |
| C-5 | Myhistine Expectorant | My-K Labs | 7.50 |
| C-5 | Mytussin DAC Syrup | My-K Labs | 1.40 |
| otc | Novahistine DMX Liquid | Lakeside | 10.00 |
| C-5 | Novahistine Expectorant | Lakeside | 7.50 |
| C-3 | Nucofed Expectorant Syrup | Beecham | 12.50 |
| C-5 | Nucofed Pediatric Expectorant Syrup | Beecham | 6.00 |
| C-3 | P-V-Tussin Syrup | Reid-Rowell | 5.00 |
| otc | Primatuss Cough Mixture 4D Liquid | Rugby | 10.00 |
| C-3 | Promist Expectorant Liquid | Russ | 5.00 |
| otc | Quelidrine Cough Syrup | Abbott | 2.00 |
| otc | Robitussin-CF Syrup | Robins | 4.75 |
| C-5 | Robitussin-DAC Syrup | Robins | 1.40 |
| Rx | Ru-Tuss Expectorant | Boots | 10.00 |
| C-3 | S-T Forte Syrup and Liquid | Scot-Tussin | 5.00 |
| C-3 | SRC Expectorant | Edwards | 12.50 |
| otc | Sudafed Cough Syrup | B-W | 2.40 |
| C-3 | Triaminic Expectorant DH | Sandoz | 5.00 |
| C-5 | Triaminic Expectorant w/Codeine | Sandoz | 5.00 |
| C-3 | Tussafin Expectorant | Rugby | 12.50 |
| C-5 | Tussar SF Cough Syrup | USV | 12.00 |
| C-5 | Tussar-2 Cough Syrup | USV | 5.00 |
| C-3 | Tussend Expectorant | Merrell Dow | 12.50 |
| PEDIATRIC COUGH PREPARATIONS | | | |
| otc | Bayer Cough Syrup For Children | Glenbrook | 5.00 |
| Rx | Carbodec DM Drops | Rugby | 0.60 |
| Rx | Cardec DM Drops | Barre | 0.60 |
| Rx | Mycadec DM Syrup | My-K Labs | 0.60 |
| otc | Myminic Expectorant | My-K Labs | 5.00 |
| otc | Naldecon-DX Pediatric Drops | Bristol | 0.60 |
| otc | Naldecon-DX Pediatric Syrup | Bristol | 5.00 |
| otc | Naldecon-Ex Syrup | Bristol | 5.00 |
| C-5 | Pediaco Cough Syrup | Winthrop | 5.00 |
| Rx | Rondec-DM Oral Drops | Ross | 0.60 |
| Rx | Tussafed Drops | Everett | 0.60 |

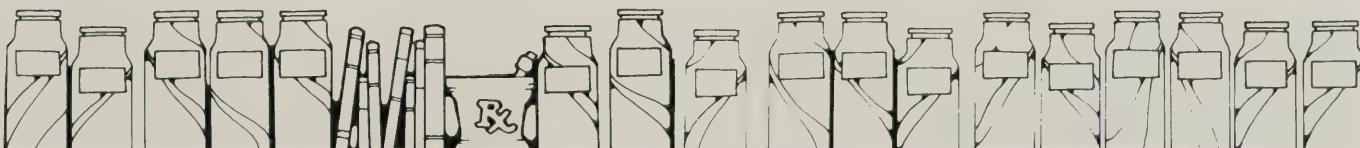


TABLE 2
Non-Alcohol Containing Cough, Cold, & Allergy Medications

| NAME OF PRODUCT | | COMPANY |
|--|--|----------------|
| BRONCHODILATORS | | |
| Rx | Aerolate Liquid | Fleming |
| Rx | Alupent Syrup | Boehringer |
| Rx | Aquaphylin Syrup | Ferndale |
| Rx | Metaprel Syrup | Dorsey |
| Rx | Slo-Phyllin Syrup | Rorer |
| Rx | Theoclear-80 Syrup | Central |
| Rx | Theolair Liquid | Riker |
| Rx | Theophyllin Oral Solution | Roxane |
| DECONGESTANT, ANTIHISTAMINE, & ANALGESIC COMBINATIONS | | |
| otc | Children's CoTylenol Liquid | McNeil |
| otc | Sinutab Maximum Strength Nighttime Sinus Formula | Warner-Lambert |
| ANTITUSSIVES | | |
| otc | Delsym | McNeil |
| otc | St. Joseph Cough Syrup | Plough |
| ANTIASTHMATIC COMBINATIONS | | |
| Rx | Dilor-G Liquid | Savage |
| Rx | Dylene-GG Liquid | Seatrace |
| Rx | Elixophyllin-GG Liquid | Forest |
| Rx | Glyceryl-T Liquid | Ruby |
| Rx | Quibron Liquid | Bristol-Myers |
| Rx | Slo-Phyllin GG Syrup | Rorer |
| Rx | Theocolate Liquid | My-K Labs |
| DECONGESTANTS & ANTIHISTAMINES | | |
| Rx | Anamine Syrup | Mayrand |
| Rx | Bromfed Syrup | Muro Pharm. |
| otc | Chlorafeed Liquid | Hauck |
| otc | Dallery-D Syrup | Laser |
| Rx | Deconamine Syrup | Berlex |
| otc | Fedahist Decongest Syrup | Kremers-Urban |
| otc | Ryna Liquid | Wallace |
| otc | Triphenyl Syrup | Ruby |

TABLE 2
Continued

| NAME OF PRODUCT | | COMPANY |
|--|---|---------------|
| ANTITUSSIVE COMBINATIONS | | |
| otc | Cremacoat 4 Liquid | Vicks |
| otc | Kolephrin NN Liquid | Pfeiffer |
| C-3 | Nucofed Syrup | Beecham |
| C-5 | Ryna-C Liquid | Wallace |
| otc | Scot-tussin DM Liquid | Scot-Tussin |
| otc | Triaminic-DM Liquid | Sandoz |
| otc | Triaminicol Multi-Symptom Cold Syrup | Sandoz |
| otc | Triminol Cough Syrup | Rugby |
| otc | Tussar DM Cough Syrup | USV |
| EXPECTORANT COMBINATIONS | | |
| otc | Codimal Expectorant | Central |
| otc | Fedahist Expectorant Syrup | Kremers-Urban |
| ANTITUSSIVES with EXPECTORANTS | | |
| C-3 | Codiclear DH Syrup | Central |
| C-3 | Entus Expectorant Syrup | Hauck |
| otc | Kolephrin GG/DM Expectorant | Pfeiffer |
| C-3 | Kwelcof Liquid | B. F. Ascher |
| otc | Silexin Cough Syrup | Clapp |
| Rx | Torganic-DM Liquid | Major |
| C-5 | Tussi-R-Gen Expectorant | Goldline |
| otc | Vicks Children's Cough Syrup | Vicks |
| ANTITUSSIVE & EXPECTORANT COMBINATIONS | | |
| otc | Anatuss Syrup | Mayrand |
| C-5 | Anatuss w/Codeine Syrup | Mayrand |
| otc | Cremacoat 3 Throat Coating Cough Mixture Liquid | Vicks |
| otc | Dexafed Cough Syrup | Hauck |
| otc | Father John's Medicine Plus Liquid | Oakhurst |
| otc | Kophane Cough & Cold Formula Syrup | Pfeiffer |
| C-5 | Naldecon-CX Liquid | Bristol |
| otc | Noratuss II Expectorant | Vortech |
| C-5 | Ryna-CX Liquid | Wallace |
| C-5 | Tussirex Sugar Free Liquid | Scot-Tussin |
| C-5 | Tussirex Syrup | Scot-Tussin |

TABLE 3
Alcohol (Ethanol) Drug Interactions

| Drug | Severity | Effect |
|-----------------|----------|-----------------------|
| Barbiturates | moderate | 1, 2, 11 |
| Benzodiazepines | minor | 3, 4, 11 |
| Cephalosporins | moderate | 5, 10, 12 |
| Chloral Hydrate | minor | 1, 6, 7 |
| Disulfiram | major | 2, 5, 7, 8, 9, 10, 12 |
| Furazolidone | moderate | 5, 10, 12 |
| Glutethimide | minor | 1, 11 |
| Meprobamate | minor | 1, 11 |
| Metronidazole | moderate | 5, 10, 12 |
| Phenothiazines | minor | 3, 4, 11 |

1. additive or synergistic CNS and respiratory depression may occur
2. effects of interaction are dose dependent
3. effects of both drugs may be increased
4. impaired psychomotor function with excessive sedation may occur
5. may produce acute alcohol intolerance
6. side effects of tachycardia, headache, and facial flushing may occur
7. avoid ethanol ingestion during concurrent administration
8. hypotension and cardiovascular collapse may occur
9. effects of interaction may occur for several days after discontinuation of drug
10. avoid ethanol ingestion
11. avoid excessive or chronic ethanol ingestion
12. symptoms include flushing, headache, papitations, tachycardia, dyspnea, hyperventilation, nausea, and vomiting



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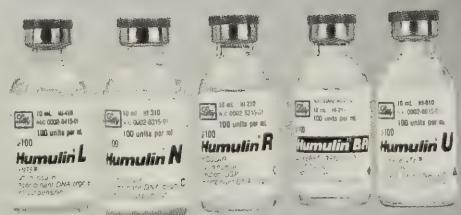
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TOO MUCH WEIGHT AND DIABETES—DEALING WITH THE DEADLY DUO

by Charles M. Peterson, M.D.
Director of Research
Sansum Medical Research Foundation
Santa Barbara, Calif.

Weight, it sometimes seems, has replaced weather as the topic about which we talk most and do least.

That's not to say Americans are not dieting. More than half are on a diet at any one time, according to most estimates. But many people in the other half must be gaining even more at the same time. Annual food consumption was 20 pounds higher per person in 1983 than in 1963. People also consumed a higher percentage of fats and oils.

For the 10 million Americans who have non-insulin-dependent diabetes, weight and what to do about it is a particularly serious problem. An estimated 80 percent of them are obese (more than 20 percent above normal body weight) when their disease is diagnosed. The excess weight can both accelerate their diabetes and bring on its complications, first and foremost cardiovascular disease and stroke.

As one of my colleagues bluntly puts it: "If you want to find out if there's a possibility of getting diabetes . . . just keep on eating and get fat . . . you (can) do other things, too, but the main thing is get fat."

In fact, the American Diabetes Association has coined the term "diabesity" to describe the overweight factor in diabetes development. In the early stages of non-insulin-dependent diabetes, by far the most common type of the disease, losing weight can actually cause diabetes to disappear.

Diet and non-insulin-dependent diabetes was the subject at a recent National Institutes of Health (NIH) consensus conference. All 14 members of the expert panel had one message for those with excess poundage: Lose it! In a news conference they went even further—recommending annual postprandial (after a meal) blood sugar tests for all overweight individuals, especially if they have a family history of diabetes.

The NIH consensus conference suggests that "moderate caloric restriction" of from 500 to 1,000 calories

below daily requirements may be helpful for overweight diabetic and not-yet-diabetic individuals alike. This is similar in calories to the low-fat "prudent diet" proposed for all adults by the American Heart Association—to defend against atherosclerosis (the build up of debris in blood vessels that leads to clots, heart attacks and strokes). Since those who have diabetes are two to three times more likely than those who don't to die of such complications, the similarity makes sense.

Does this mean that a single diet may be effective against two major causes of death—heart disease and diabetes?

Unfortunately, things are seldom so simple. True, the "prudent diet" can lower both blood sugar and blood fats. However, reducing fat to 30 percent of the calories we consume, as recommended, raises carbohydrates to 50 to 60 percent of the diet since protein remains at 10 to 20 percent. This increase may not be good for all non-insulin-dependent diabetes patients.

The higher carbohydrate levels may actually promote atherosclerosis and high blood pressure in some patients. How? By lowering protective HDL (high-density lipoprotein) and increasing the risk-raising LDL and VLDL (low- and very-low-density lipoproteins). In addition, such diets often raise blood sugar—that other risk factor for vascular disease.

Just losing weight will raise HDL and reduce other blood fats as well as blood sugar, emphasizes the NIH panel. Once the blood sugar is normal, diabetic patients can reduce dietary fats further in search of lower VLDL and LDL cholesterol, lower triglycerides and diminished atherosclerosis risk. Recent studies also suggest cutting back on protein may help those with kidney disease.

One panel recommendation gives the diabetic individual the chance to eat more the way the rest of us do. Some sugar (sucrose) as a "taste additive" is OK—if

this doesn't raise the blood sugar (glucose) levels and if the person is not overweight. Persons with "diabesity" must still count the calories and use sugar only to the extent that it does not raise blood sugar.

The NIH panel called studies of fiber's ability to lower blood sugar and cholesterol inconclusive and emphasized that patients on a high-fiber diet may not absorb calcium and other minerals properly—leading to brittle bones. Diabetic individuals with nerve damage may not notice gastrointestinal irritation and damage from fiber (roughage). For those who want to replace other carbohydrates with fiber, the panel suggests soluble fibers (barley, beans, peas) rather than bran (insoluble) or purified supplements.

Carbohydrates in certain foods, like potatoes, raise blood sugar more rapidly than those in others—rice and lentils, for instance. However, so many other factors—cooking time, storage, processing, other foods in a meal—interact with specific carbohydrate-containing foods that the NIH panel concludes ranking foods by this "glycemic index" is unreliable. Nevertheless, each individual with diabetes is encouraged to document his or her own responses to different foods with an after-meal glucose check.

Disagreement among experts over different dieting strategies probably contributes to the hot-and-cold attitude of Americans toward losing weight, whether or not they have diabetes. However, all the experts agree with dieters on the major reason for not getting or keeping pounds off—it's very, very difficult to do.

Many possible explanations are being explored. Genes appear to play a part in both obesity and diabetic obesity, though fatness is not inherited as blue eyes are. Some people may be "food efficient," able to store food energy as fat and resist losing it when the body demands more energy. In addition, researchers have found that nervous system defects may scramble signals that mean "stop eating; you've had enough" or "burn up those extra calories; don't store them." Meanwhile, opposing signals to "overeat!" may be coming from the body's fat cells themselves.

A biologic system that regulates body weight has probably been around unchanged a long time. However, until it's identified and understood there's obviously no way to change it to meet today's demands.

Feel you can't beat the system? Don't throw up your hands so quickly. Though "crash" diets and "miracle" weight loss formulas generally don't succeed in the long term and may be dangerous, behavior change can be produced by psychological counseling, nutritional education, peer group (people with the same problem) support and access to information and lower calorie foods. Losing weight is *not* just a matter of "willpower," as so long believed.

Here are some simple tricks that can help:

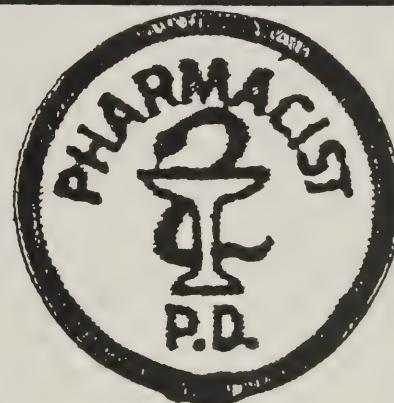
- Learn what triggers your eating. Then learn to control these cues.

- Don't keep large amounts of food on hand.
- Prepare meals rather than pick up a convenient snack.

What about exercise to lower weight in diabetic individuals? First of all, exercise without restricting calories doesn't result in weight loss. Its effects on blood sugar are, according to the NIH panel, quite variable and depend on the individual and the type of exercise, such as leg flexibility, strength training or cardiovascular conditioning. Exercise that requires straining and breath holding, like weight lifting, can be risky for patients with retinopathy (eye damage), high blood pressure and heart problems. Conditioning exercise, however, makes sense because of its cardiovascular benefits. Patients should choose something they can enjoy and expect to do often and over a lifetime, but not until they've been medically evaluated.

At the close of the NIH consensus conference on non-insulin-dependent diabetes and diet, George F. Cahill, M.D., vice president of the Howard Hughes Medical Institute, told reporters, "The biggest favor diabetics can do themselves is to lose weight and, should they regain it, take it off again."

I would add only that losing weight is also the biggest favor that those overweight and at risk of developing diabetes or heart disease can do themselves.



ACTUAL SIZE

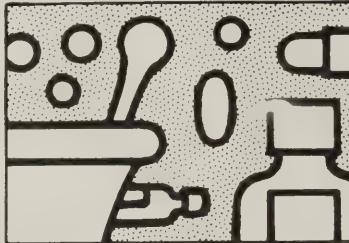
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Things You Should Know FOR YOUR GOOD HEALTH



Medication Can Change Your Spirits

The holiday season is once again upon us and finds many of us attending those traditional family gatherings and office parties. Often accompanying the holiday joy and merriment is the consumption of liquid spirits — alcohol. The moderate imbibing of alcoholic beverages may not be the cause of great concern for you, however, if you are taking prescription or over-the-counter medications, you may need to change your traditional holiday habits concerning alcohol.

Alcoholic beverages act on the brain as depressants, temporarily decreasing coordination, alertness, breathing, and sometimes causing vision to become blurred. Certain medicines your physician may prescribe or your pharmacist may recommend can increase the effects of alcohol. These increased effects are known as "interactions." Some of the more common interactions are noted below.

Diabetes Medications — Some patients who drink alcohol while taking medication for diabetes may suffer stomach pain, nausea, vomiting, dizziness, sweating or flushing (redness of face and skin). In addition, alcohol may produce hypoglycemia (low blood

sugar).

High Blood Pressure Medicines — Alcoholic beverages may exaggerate the degree to which some high blood pressure medications lower your blood pressure, causing lightheadedness or dizziness.

Pain Medications — Some pain medications (for example those containing codeine) cause, as a side effect, drowsiness, dizziness, or blurred vision. Alcohol, taken in combination with these pain relievers, will cause this depressant side effect to intensify far beyond the effect of either taken alone.

Anti-arthritis Medications — Many of the drug products taken for pain relief caused by arthritis can, by themselves, upset your stomach. When taken along with an alcoholic beverage this stomach upset could be much more severe.

Many other medications such as those for your heart, allergies, ulcers, or infections may interact with alcohol. Therefore, it's a very good idea to avoid alcoholic beverages when taking any medications. But, if you get the urge to have a cocktail or two during this holiday season, talk to your pharmacist first. It's for your good health.

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Kathie Mantine, Frederick County Pharmaceutical Association President and William Suanner (Ayerst) at the recent FCPA breakfast Meeting. Thirty pharmacists attended.



At the MPhA Mid Year Meeting in Annapolis Stephanie Rutten Cox receives the University of Maryland School of Pharmacy Scholarship Award. Tony Kearny of Giant sponsored the award.



Nick Lykos, of Lykos Pharmacy in Timonium, has been re-elected by the MPhA Membership as Treasurer for 1988-1989.



Electron micrograph of the internal structure of a renal interstitial cell. The dark granules in the picture contain lipids which are believed to be antihypertensive substances.

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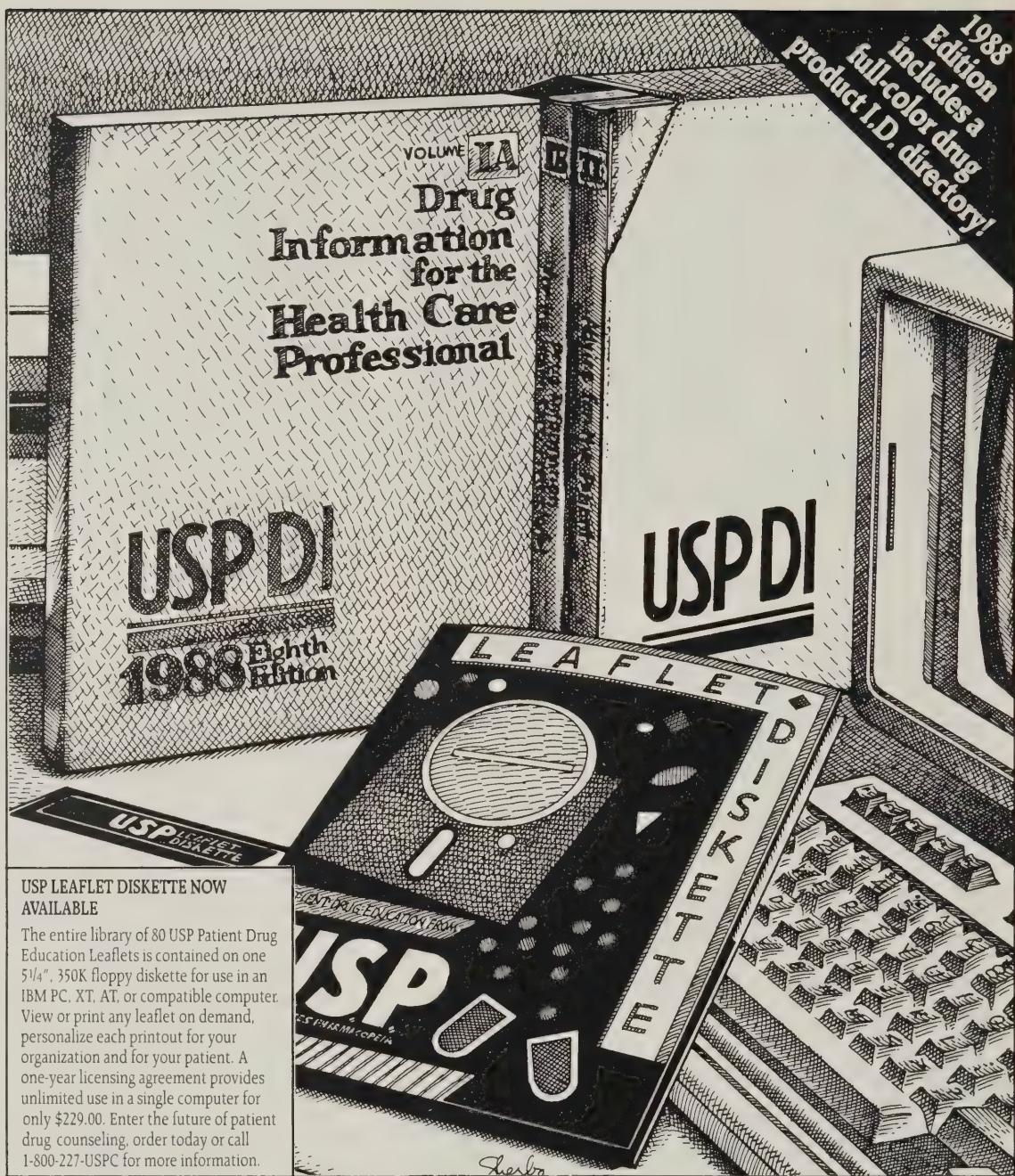
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"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

LAMBDA KAPPA SIGMA sorority is planning its 75th Anniversary, August 2-6, 1988 at the Copley Plaza Hotel in Boston. All LKS sisters are encouraged to come and celebrate the future of LKS and women in pharmacy. For details, contact Mary Greer at Lambda Kappa Sigma, P.O. Box 981, Claremont, OK 74018.

SPECIAL SEMINAR PLANNED on "Teaching People with Low Literacy Skills: A Workshop for Health Professionals" for April 14, 1988, 8:30 a.m. to 4:00 p.m. at the Lord Baltimore Hotel. For registration information, contact Phyllis Wood, R.N., M.P.H. at 532-3838.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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Next Month.
High Blood Pressure Month

calendar



- April 19—CECC—Dermatology in Elderly 8 am—Martin's West
April 28—Osteoporosis Lectures 6:30 pm—see story
May 4—Alumni Annual Meeting and Election 8:30 pm
May 12—MPhA Board Meeting—Kelly Building
May 12—MSHP Meeting—Johns Hopkins Hospital
May 16, 17—NARD Legislative Conference—Washington
May 19—Alumni Association Graduation Banquet 6 pm
May 20—Graduation—Class of 1988
June 5—CECC—Substance Abuse Among Pharmacy Staff
June 5-9—ASHP Annual Meeting—San Francisco
June 12—AZO Installation Dinner Meeting
June 19-23—MPhA Convention—Sheraton, Ocean City



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May is High Blood Pressure Month

THE MARYLAND PHARMACIST

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In the New York Times Magazine of April 17, 1988, the headline proclaims:

The Druggist's Crucial New Role: Today's Pharmacists must help people monitor their use of medication.

Our own Maddy Feinberg is pictured on the lead page and pharmacists and patients from all over the country are quoted as to the need for more frequent and better monitoring of patients on chronic care medications. This role is not new, but is certainly a crucial one if the increasing numbers of non-institutionalized patients are to get the benefits of those millions of prescriptions that we dispense each year. An article beginning on page 10 of this issue of the Maryland Pharmacists I details some of the ways that this may occur. The concern is no longer whether increased pharmacy services are needed, but rather how they can be provided in the milieu of a busy community practice.

The Changing Practice of Pharmacy in the Community

In my many years both in practice and in researching practice, I have developed a profound respect for you, the men and women in pharmacy who are constantly buffeted by conflicting demands to do more and more, faster and faster, and for less and less. And I am also aware of the increasing numbers who are despairing that they cannot meet the expectations of all, especially of those who appear to be more concerned with "cost containment" (translate as *their* bottom line) than on patient care.

What can we do to meet the needs and still survive in the era of cost containment? There are no simple answers. But, I am convinced that each of us in our daily practice can find time to provide service to those most at risk—and do it in a cost effective way.

May is High Blood Pressure Month. It has been demonstrated that pharmacists can improve the control of treated hypertensives even in a busy practice. The challenge is to expand such services to all of those in need. This is one challenge that we cannot forsake.

Donald O. Fedder

Continuing Education

Advising Consumers on Fish Oil for Prevention of Coronary Heart Disease

2. provide information on polyunsaturated fatty acids derived from oily fish, as suspected means to reduce the incidence of coronary heart disease, and explain probable mechanisms for this protection.

Objectives

At the conclusion of this lesson, participants will be able to:

1. define the action of polyunsaturated fatty acids derived from fish oil on various plasma lipids and cholesterol, and platelet function;
2. single out specific effects that are proposed for these fatty acid supplements; and
3. explain how to counsel consumers on the benefits/risks of OTC products that contain fish oil-derived polyunsaturated fatty acids.

Cardiovascular disease is the primary cause of death in the Western world. Recently, evidence has shown that development of cardiovascular disease can be modified by dietary means. Specifically, a dietary intake rich in polyunsaturated fatty acids has been reported to reduce its rate of occurrence, and this in turn is believed to reduce the mortality rate of cardiovascular disease.

Newspapers, radio and television are reporting these findings to consumers. Articles in consumer magazines suggest ingesting, at minimum, two meals per week of fish from deep-sea, cold water origin. Several OTC fish oil dietary supplement products are promoted as acceptable substitutes for fish meals.

The professional literature also contains numerous reports of suspected medical benefits from eating fish and/or taking fish oil-derived products for dietary supplementation. However, authorities acknowledge that they do not know the long-term ramifications of this. Specific problems are cited which suggest

that a diet rich in polyunsaturated fatty acids from fish oils may actually have detrimental health consequences if undertaken without medical supervision.

Health food stores have been selling fish oil supplement products for several years. Only recently have similar products appeared on pharmacy shelves. (Table 1.)

Epidemiologic Support for a Fish Oil Diet

Most investigations of polyunsaturated fatty acids have focused on polyunsaturated fatty acids of vegetable origin, such as corn and safflower oils. These contain a high proportion of the omega-6 fatty acid, linoleic acid.

More recently, however, fish oils have been seriously considered as a major source of polyunsaturated fatty acids. The metabolic differences between fatty acids derived from vegetable and fish origin are only beginning to be recognized and appreciated.

TABLE 1

| OTC Fish Oil Supplement Products | |
|-----------------------------------|--|
| Product (Mfr.) | Contents (per capsule) |
| MaxEPA (R.P. Scherer Corp.) | Eicosapentaenoic acid 180 mg Docosahexaenoic acid 120 mg Vitamin A less than 100 I.U./g Vitamin D less than 10 I.U./g |
| Promega (Parke-Davis) | Eicosapentaenoic acid 350 mg Docosahexaenoic acid 150 mg |
| Proto-chol (Squibb) | Eicosapentaenoic acid 180 mg Docosahexaenoic acid 120 mg |

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
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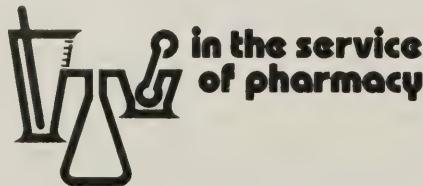
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Goals

The goals of this lesson are to:

1. discuss the meaning of various terms that describe lipids, and tell how these relate to the etiology of coronary heart disease;



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While both safflower oil and salmon oil, for example, lower the total plasma cholesterol and low density lipoproteins (LDL) in normal subjects, only the marine-derived oil also decreases plasma triglycerides and very low density lipoproteins (VLDL). These latter activities are needed for the long-term effect of lowered blood lipid levels.

The FDA reports that fish oils are 2 to 5 times more effective in lowering blood cholesterol than polyunsaturated oils of vegetable origin.

Numerous data from epidemiologic investigation strongly suggest that persons living in areas where diets are rich in fish oils have significantly lower death rates from coronary heart disease. It is unclear whether this results from inhibition of platelet aggregation and decreased arterial thrombosis, or to a reduction in the atherosclerotic process itself. Both processes may be beneficially affected; there may be other influences as well.

The first recorded incidence relating the high consumption of fish to a low death rate from coronary heart disease was noted with Greenland Eskimos in 1913. It was observed that Eskimos have longer bleeding times, lower serum triglyceride and total cholesterol levels, and elevated high density lipoprotein (HDL) cholesterol levels as compared with persons ingesting diets low in fish content.

The diet of Eskimos is rich in oily fish (averaging 400 gm/day) as well as seal and whale flesh. While the meat of these marine animals is high in cholesterol and fat, the fat is unique in that it contains an abundant amount of long-chain, polyunsaturated fatty acids of the omega-3 series (Figure 1).

The dietary habits of Eskimos and Americans differ significantly. First, the Eskimo diet is lower in saturated fatty acids. Second, and more importantly, the major polyunsaturated fatty acids in the Eskimo diet are of the omega-3 type. These consist mainly of eicosapentaenoic acid (20:5 omega-3)* (EPA) and docosahexaenoic acid (22:6 omega-3) (DHA).

In contrast, Americans consume a large amount of saturated fatty acids from animal sources. The predominant polyunsaturated fatty acid is linoleic acid (18:2 omega-6), derived from vegetable origin.

The Japanese also have a relatively low death rate from coronary heart disease. Their diet is rich in fish, averaging 100 gm/day. And within Japan, the lowest mortality rate from coronary heart disease occurs on the island of Okinawa, where the average daily fish consumption is double that of the rest of the Japanese nation.

An interesting study followed the eating habits of men living in Zutphen, The Netherlands. Dietary habits of 852 middle-age men were determined in 1960. During 20 years of follow-up, an inverse dose-response relationship was noted between the quantity of fish consumed and the death rate from coronary heart disease. This death rate was less than half in men who consumed at least

*The number left of the colon designates the number of total carbon atoms. That to the right of the colon identifies the number of double bonds. The final number designates the location of the first double bond, counting from the methyl end of the carbon chain.

30 gm/day fish, versus those who did not eat fish.

The report is of interest in that it was prospective in design, and the average daily ingestion of a relatively minimal quantity of fish, 30 gm, had a substantial protective effect. The inverse relationship between fish consumption and death from coronary heart disease was authentic over the entire range of fish intake.

Further, the protective action of fish was independent of other variables such as blood pressure, age, and serum cholesterol levels. The investigators, therefore, concluded that consuming as little as two meals of fish each week may significantly reduce the incidence of death from coronary heart disease.

In another study, thirteen patients with ischemic heart disease continued their normal diet, medication and smoking habits. Each received EPA 3.5 gm/day. At 5 weeks, the subjects experienced a 10 percent increased platelet survival time, 15 percent decreased platelet count, 75 percent reduction in plasma levels of platelet factor IV, and 30 percent decrease in plasma beta-thromboglobulin. From these changes, it was speculated that consumption of omega-3 polyunsaturated fatty acids (such as EPA) will minimize platelet/vessel wall interactions, and reduce the risk of ischemic heart disease.

Several short-term investigations have explored the potentially beneficial action of fish diets and fish oil. In one group of 19 men and 23 women who were all lacto-ovo-vegetarians (include milk and eggs, but exclude meat, fish, and poultry flesh from the diet), substituting mackerel (equivalent to 8 gm/day of omega-3 fatty acids) for cheese in their diets for three weeks, resulted in decreased plasma triglyceride and cholesterol levels. In the men, but not the women, this substitution also increased LDL and HDL cholesterol.

In another investigation, seven healthy men demonstrated decreased platelet aggregation and thromboxane A₂ formation, and lowered plasma cholesterol and triglyceride levels after eating a diet of mackerel, equivalent to 7 to 11 gm EPA/day. In a separate study, 12 volunteers who ingested cod liver oil

Fatty Acid Nomenclature and Dietary Sources

| Family | Fatty Acid | Structure | |
|---------|--|--|-----------------------------|
| omega-3 | Eicosapentaenoic Acid (C20:5 omega-3) | H ₃ C  RCOOH | Marine Oils, Fish |
| omega-6 | Linoleic Acid (C18:2 omega-6) | H ₃ C  RCOOH | Vegetable Oils |
| omega-9 | Oleic Acid (C18:1 omega-9) | H ₃ C  RCOOH | Vegetable Oils; Animal Fats |

Figure 1. The major polyunsaturated fatty acids families. A common member of each of the three families is shown. (NEJM 312:1211, 1985)

containing 1.8 gm/day of EPA and 2.2 gm/day of DHA for six weeks had reduced plasma triglyceride and increased HDL cholesterol, prolonged bleeding times and decreased platelet aggregation activity.

Clinical trials with fish oil supplements have shown that changes in the relative content of plasma lipid fatty acids are evident within 2 days of initiating consumption. These changes also become more evident as consumption continues. Following cessation of fish oil ingestion, plasma fatty acid levels return to baseline within a few days to a couple weeks.

Lipids and Coronary Heart Disease

Hyperlipidemia is defined as an elevation of one or more plasma lipids. The major lipids (cholesterol, triglycerides and phospholipids) circulate in the blood attached to protein carriers termed lipoprotein. Lipids are not water soluble in their free state, but attached to protein, they are made soluble for transport as lipoproteins.

Classification of Lipoproteins. Lipoproteins may be classified by density (weight). They include chylomicrons, VLDL, LDL, and HDL.

VLDL and LDL are correlated posi-

There are two series of essential fatty acids, the omega-6 and omega-3, derived from linoleic (18:2 omega-6) and linolenic (18:3 omega-3) respectively. These cannot be synthesized de novo in animal tissues. Both can undergo desaturation and chain elongation to form C₂₀₋₂₂ derivatives. No interconversion occurs between omega-6 and omega-3 fatty acids.

Linoleic acid is an essential nutrient. Two of its derivatives, EPA (20:3 omega-6) and arachidonic (20:4 omega-6) acids, are components of cell membranes. They are also precursors of prostaglandins and leucotrienes. DHA is one of the most abundant fatty acids in the human brain.

Many vegetable oils that are advertised as "high in polyunsaturated fats" contain an abundance of linoleic over linolenic acids. Consuming a diet rich in these fats suppresses conversion of linolenic into EPA and DHA.

tively with development of atherosclerosis. The contemporary feeling is that elevated levels of HDL may actually reduce the risk of coronary heart disease. The higher the ratio of HDL to LDL, the greater the protection against coronary heart disease.

The mechanism for this activity is unclear, and in fact, it is not clear if the response is significant. One popular presumption is that HDL transports cholesterol from tissues to the liver where it is degraded and later excreted. An alternative hypothesis suggests that HDL inhibits cholesterol uptake by smooth muscle cells, thus preventing plaque formation.

When lipid accumulates on arterial walls, partial or complete occlusion of the artery may occur. This is the beginning of coronary heart disease.

Proposed Mechanisms of Action

The precise mechanism for protection from cardiovascular disease by fish oils is unknown, but there are two explanations. First, there is a reduction in plasma triglyceride, VLDL and LDL, and increase in HDL. Second, the fish oil derivatives induce changes in platelet behavior. These are elaborated below.

It is known that approximately half of all persons with atherosclerosis have shortened platelet survival times due to increased platelet turnover. This may encourage further plaque development because of release of fibroblast-stimulation growth factors from platelets.

Platelet Aggregation Property. Key steps in the pathway for synthesis of prostacyclin (PGI₂) and thromboxane (TXA₂) are shown in Figure 2.

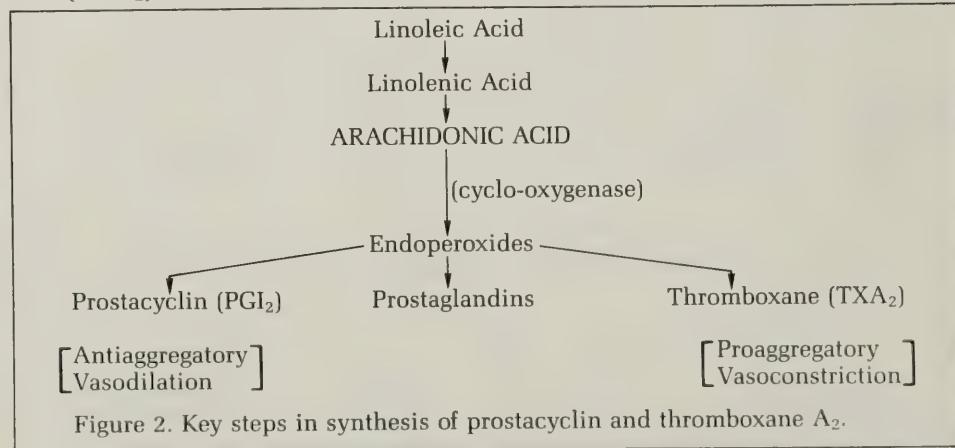


Figure 2. Key steps in synthesis of prostacyclin and thromboxane A₂.

When EPA is substituted for arachidonic acid in platelet membranes, the two fatty acids compete for cyclo-oxygenase. Both EPA and arachidonic acid have approximately equal affinities for the enzyme. But EPA is transformed much more slowly than arachidonic acid to endoperoxides.

So, the primary action of EPA is by competitive inhibition of cyclooxygenase. Some EPA is also probably metabolized to TXA₃, which is less active than TXA₂, but may inhibit action of TXA₂ by competitive inhibition. Overall, when EPA is taken, prostaglandin synthesis patterns are altered; platelet aggregation is reduced and bleeding time is increased.

Triglyceride. Most clinical trials have demonstrated decreases in plasma triglyceride when fatty fish was consumed. A diet of 200 to 600 gm of fish/week for 3 months resulted in a 7 percent drop. A mackerel diet of 280 gm/day for 2 weeks resulted in a 47 percent decrease in another study. In other trials, supplementation with MaxEPA (refer to Table 1) 5 gm/day for 3 weeks resulted in a 14 percent decrease, and 20 gm/day for 8 weeks caused a 51 percent decrease.

The most likely mechanism is that the polyunsaturated fatty acid decreases hepatic VLDL synthesis. An alternative mechanism is that it increases VLDL clearance out of the body.

Plasma Cholesterol. The beneficial response of dietary fish oils appears to depend on the type of treatment and quantity ingested. There was no significant effect on total cholesterol in one study when cod liver oil was used. But significant effects

were seen when high intakes of other fatty fish or MaxEPA were consumed. The greatest reductions in plasma cholesterol were seen in hypertriglyceridemic individuals who consumed fish oil diets for 4 weeks or longer.

HDL Cholesterol. Evidence from animal experiments suggests that HDL cholesterol may be more sensitive to DHA than EPA. For example, HDL levels increased 11 percent when 100 mg/day DHA was given to rodents for 2 weeks. The same quantity of EPA resulted in no appreciable effect on HDL cholesterol. In most clinical studies, results have shown that only a slight rise in HDL occurs, except at high doses.

LDL and VLDL Cholesterol. Only a few studies have investigated the effects of fish oil on VLDL or LDL levels. Reduced synthesis of VLDL probably accounts for lowered LDL levels.

Thus far, most emphasis has centered on EPA; very little attention has focused on DHA. But preliminary work has shown that dietary DHA converts to EPA in humans. If these data are significant, then DHA ingestion may serve as a source of EPA.

To date, studies on fish oil have concentrated on EPA and DHA fatty acids. There may be other beneficial constituents of natural fish oil that have not yet been identified. Whether these substances, if any, would also be present in the commercial products is unknown.

Experimental Protocols

Many of the clinical trials conducted to date have limited value due to poor experimental design.

Then there is a more practical issue. In many of the clinical trials, the quantity of fish consumed and resulting omega-3 polyunsaturated fatty acid intakes have greatly exceeded what would reasonably be consumed by the American public.

For example, the average per capita consumption of fish in the U.S. is estimated to be 13 pounds/year. Compare this to Eskimos who consume more than 3/4 pound/day and the Japanese who ingest approximately 1/4 pound/day. (Surveys conducted by the World Food and Agri-

culture Organization indicate that the average ingestion of fish worldwide is slightly over one ounce/day.) If fish consumption by Americans reached 225 gm/day (equivalent to two daily servings of 1/4 pound at each serving) and all of it was in the form of fatty fish, EPA intake would approximate only 1.5 gm/day. In most clinical studies, volunteers have consumed daily quantities of this fatty acid ranging to 20 gm or more.

Cod Liver Oil. One literature citation contains a recommendation for ingesting cod liver oil, 40 ml/day, as a source of omega-3 polyunsaturated acids. Cod liver oil contains approximately 9 percent EPA and 6 percent DHA. It also contains vitamins A and D, commonly 4,250 I.U. vitamin A, and 425 I.U. vitamin D per 5 ml. This translates to ingestion of 34,000 I.U. vitamin A and 3,400 I.U. vitamin D in this quantity of cod liver oil per day. While most individuals can tolerate these quantities of vitamins without toxic sequelae, others may not. This would be especially important to persons also taking supplements containing large doses of vitamins A and D, or ingesting a diet rich in them.

Finally, there are no studies to identify potential toxicity related to long-term, high quantity fish or omega-3 polyunsaturated fatty acid consumption. Also, it is not known whether this consumption of fish actually increases mortality from other causes, such as cancer.

Specific Safety Issues

The safety of ingesting high doses of omega-3 fatty acid supplements is unknown. Results of animal investigation suggest that adverse reactions are possible. For example, mackerel oil was hepatotoxic in pigs. Cetoleic acid (a component of fish oil, present in 1 percent concentration in commercial preparations) was cardiotoxic to rats.

Dietary supplementation with fish oil aggravates symptoms of vitamin E deficiency in animals. Administering vitamin E along with fish oil does not reverse the condition. Several studies have confirmed that thrombocytopenia may develop in humans on a diet rich in omega-3 fatty acids.

Counseling Consumers

Increasing the quantity of fish in the diet has advantages. Fish is relatively low in calories and high in protein. All fish, fresh or frozen, regardless of origin (freshwater or salt-water) or environments (cold or warm), provide some benefit. But those from cold oceanic origin, such as tuna, herring, sardines, mackerel, pilchard and salmon have the greatest content of omega-3 fatty acids, and thus, greatest potential advantage. Even lobster and other shellfish that have long been regarded as rich sources of cholesterol, contain less cholesterol per serving than a single egg. And more importantly, they have omega-3 fatty acids.

The use of long-chain polyunsaturated fatty acids of the omega-3 type may offer the best dietary means for lowering plasma triglycerides and treating hypertriglyceridemia.

There currently is insufficient evidence to support the conclusive observation that fish oil supplements have beneficial action. And since manufacturers have insufficient evidence to prove effectiveness of their products, they are labeled "dietary supplements" rather than "drugs."

Persons with disorders of lipid metabolism and coronary heart disease should be monitored by a physician. Consumers can take the OTC products as dietary supplements, but this should be done in conjunction with a physician's care, and adherence to a closely regulated program of diet/exercise and medication.

Recommendations for moderate increase in fish consumption are scarcely contestable. However, there are other factors. Coronary heart disease has been repeatedly shown to be correlated with smoking, lack of exercise, sodium intake, alcohol and excessive total dietary fat and cholesterol. Recently, a positive correlation was shown with coffee. Increasing omega-3 fatty acid intake alone, without modifying these other factors, will not provide the protection consumers desire.



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The Pharmacist and High Blood Pressure

Donald O. Fedder, Pharm.B.S., Dr.P.H.

High blood pressure (HBP) is a public problem of major proportions affecting almost 60 million Americans. But, as public health problems go, HBP is a "good" problem in that, although neither the cause nor the cure are known, HBP can be controlled. When controlled, the consequences can be ameliorated so that the person's risk for premature disability and/or death is reduced to that of one whose blood pressure is the "normal" range. Yet, HBP, smoking and high blood cholesterol are the major risk factors for two of the leading causes of death in this country: heart and cerebrovascular disease. Other significant risk factors include obesity and sedentary lifestyle. Diseases of the heart and vascular system kill almost as many persons in the United States as do all other causes combined.

If hypertension is left untreated, serious complications may occur, including congestive heart failure, stroke, renal failure and myocardial infarction. The ten year risk of death and disability is double for persons having one of the three major risk factors, triple if one possesses two risk factors, and is five times greater for those having all three.

What Constitutes HBP?

The 1988 report of the Joint National Committee on Detection, Evaluation, and Treatment of HBP (JNC IV) appointed by the National High Blood Pressure Coordinating Committee of the National Heart, Lung, and Blood Institute (NHLBI), established a national consensus on HBP. The charge of the JNC was to readvise the National HBP Education Program on issues of HBP management and control. Specifically, it was to review the 1984 report of JNC III in light of recent studies and therapeutic advances. JNC III included recommendations of some of the most difficult issues, including:

- Classification of blood pressure levels by risk
- Use of nonpharmacologic therapies for reducing associated risk factors
- Management of special populations not previously addressed, including blacks, children and pregnant women.

In addition, JNC III reviewed and made recommendations about the use of available antihypertensive agents, their dosage, side effects, and special considerations for use.

A major conclusion reached by JNC III was establishing the definition of HBP as $>140/90$ mmHg for all age groups, and defining treatment as nonpharmacologic, pharmacologic or combinations of both. Although not able to resolve all controversies as to when and how aggressively to treat with drugs, they were unequivocal that patients with BP levels at either >140 systolic BP or >90 diastolic BP were at increased risk for the sequelae of uncontrolled blood pressure and therefore should be placed in the treatment system. What has been laid to rest is the concept that "mild" hypertension is benign and can be ignored. In fact, JNC III identified a new category of increased risk which it called "high normal." This category is consistent with evidence that persons whose diastolic BP range is between 85–89 mmHg may be "pre-" or early hypertensives. This suggests that they should adopt some lifestyle changes (non-pharm treatment) to attempt to lower their BP below 85 mmHg. Such recommendations remain controversial, especially since they are difficult to operationalize. Should "high normal" be listed on an insurance application or an employment examination? What effect will labeling have on such a large number of "normal" persons? It appears that the basis for the category is the recognition that BP risk is linear; i.e., the higher the BP the greater the risk, and conversely the lower the BP the lower the risk. Blood pressure tends to increase with age, and persons, especially young adults, with BP readings in the high normal range, should be monitored. JNC III recommends BP checks at least once every two years for high normals.

JNC IV did not change the JNC III definitions of BP nor change its recommendations that treatment include both non-drug and drug therapy. It did expand the number of drugs to be considered as step one agents to include ACE inhibitors and calcium channel blockers in addition to thiazide diuretics and beta blockers. It clar-

fied somewhat the controversial areas surrounding the treatment of mild hypertension as follows:

Patients whose DBPs fall between 90 and 94 mmHg and who are otherwise at relatively low risk of developing cardiovascular disease should be *treated with nonpharmacologic approaches*. Some experts believe that drug therapy should be initiated in these patients if the DBP remains above 90 mmHg despite vigorous attempts with nonpharmacologic approaches. Physicians who elect *NOT* to use drug therapy for patients in the 90 to 94 mmHg range *should monitor their patients closely*, since some will progress to higher levels of BP that clearly warrant antihypertensive drug therapy (underlining and caps added).

They further recommended that patients with mild hypertension who have had good BP control for at least a year should have their BP medications reduced in "a stepwise fashion," especially those who are also following the non-drug therapy recommendations.

The full report, published in the May, 1988 issue of *Archives of Internal Medicine*, should be read in its entirety by all persons who are in regular contact with hypertensive patients under treatment. Reprints will be available soon from either the author, the Maryland Commission on HBP and Related Cardiovascular Risk Factors and/or the American Heart Association-Maryland Affiliate.

Patient adherence has been widely identified as a major problem in the control of hypertension. There is little debate that improvement in morbidity and mortality rates from cardiovascular disease (CVD) can be achieved by improving blood pressure (BP) control, lowering blood cholesterol, decreasing sodium and fat intake in the diet, and increasing exercise levels among the entire population. A major element in achieving the foregoing involves changing the way many, and perhaps most of the population behave. Many terms are used, such as life style changes, behavioral modification, risk factor modification, and especially patient compliance or adherence. Persons under treatment for HBP have both a greater need for and a greater degree of behavioral changes to make. These, for the most part are under frequent contact with pharmacists and thus can be helped by them. A common perception is that if patients would comply with their therapy regimen, we would see remarkable progress in decreasing premature death and disability from CVD. It is becoming increasingly apparent that this simple sounding plaint involves great complexity and varying approaches need to be better understood before many more strides can be made.

The Patient's Burden

The Patient-Practitioner Behavioral (PPB) Model illustrates the complexities in even the most simple of chronic regimens, one tablet a day therapy (Figure 1). (1) In the example, a patient initiates a physician visit. The physician examines the patient, prescribes 30 tablets of a drug to be taken once daily, authorizes one refill and instructs the patient to return in 60 days for a re-evaluation. The patient must accept the prescription, take it to a pharmacy for filling, take a tablet each day, have the prescription refilled in a timely manner so that he/she will continue to take the tablets for an additional 30 days (until the next appointment). He then must make the appointment and keep it. If all goes well, there are 65 separate tasks that the patient must perform during the long period (60 days) between doctor visits. One cannot assume that these tasks will all be performed. It has been reported that as many as 30% of prescriptions written are not filled by patients. Although anecdotal, perusal of pharmacy "will-call" bins will find many prescriptions that were not picked up by even well intentioned patients.

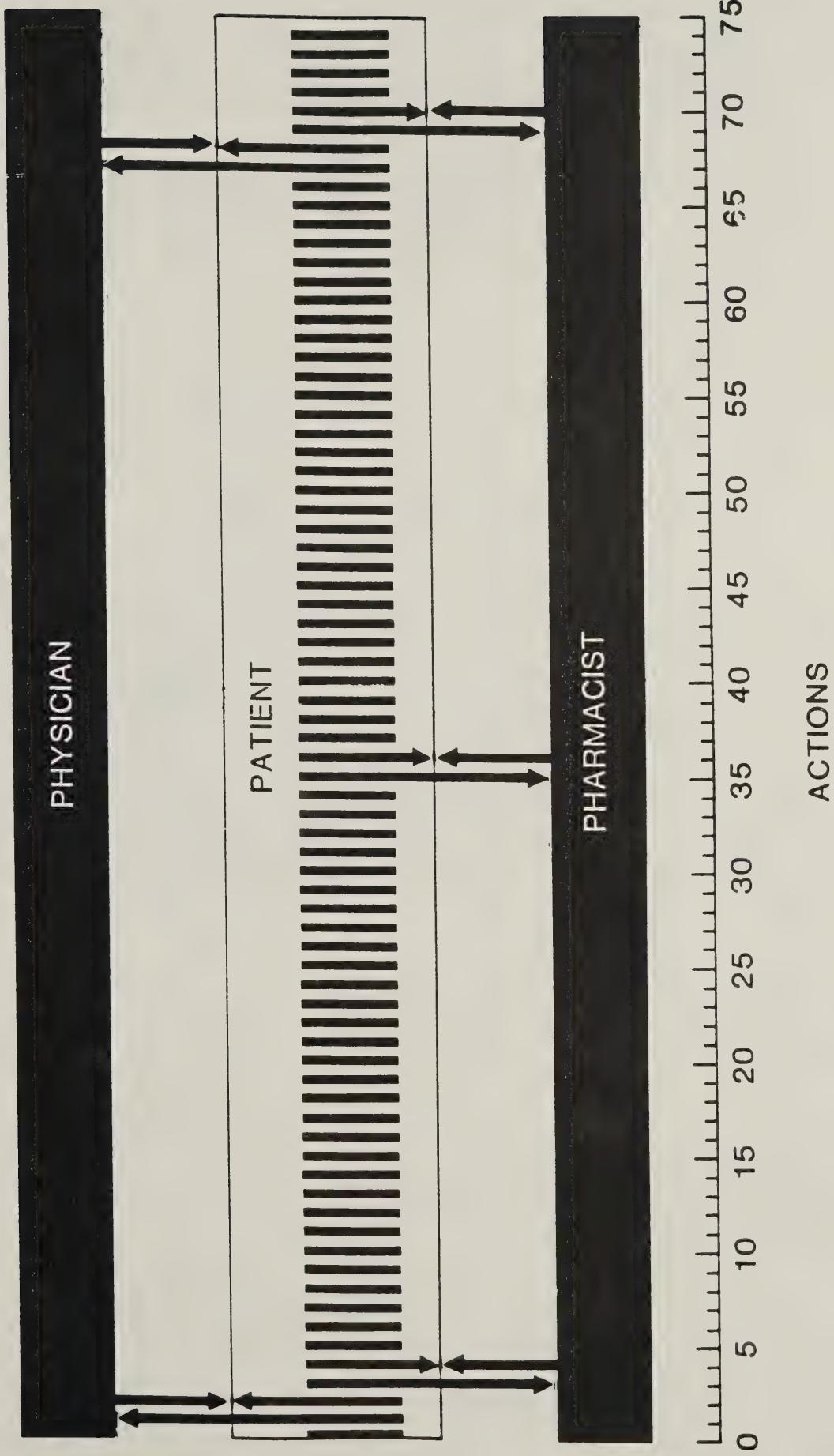
In addition, there is some evidence that most refillable prescriptions are not refilled. An unpublished survey of 118,000 prescriptions in 5 pharmacies found that 79% of the refillable prescriptions had not been refilled, at a cost to these pharmacies of over \$1.5 million dollars in one year. Although this was a "quick and dirty" review of computer records with no weighting or controls, it is consistent with anecdotal reports and provides a strong indication that patients do not necessarily have their prescriptions refilled even when authorized. Many of those who do, fail to have their prescription refilled before or by the date when their supply will be exhausted as determined by label instructions (the refill due date). Making and keeping appointments with busy practitioners is problematic so that arriving at the appointed time is certainly not assured. If either the patient or physician's schedules do not mesh, what will occur if the appointment is 10–20 days late? Some patients call the doctor or pharmacist while others will simply run out of pills.

This suggests that even the simplest chronic care therapy can be difficult for some patients and that the "burden" for compliance is borne primarily by the patient. Since the patient is in frequent contact with pharmacists during those relatively long unsupervised periods between physician visits, it was suggested that he/she might be able to help keep the patient under control. It further suggests that all practitioners need to be more sensitive to patients' needs and implement strategies and systems to improve their patient's lot.

From the foregoing, it is apparent that HBP has a number of consequences, that affect society at all

Continued on Page 12

The Complexity of Hypertension Monitoring



levels—the community, the patient and the professional. From the pharmacist's perspective, the benefits of intervening with patients under drug therapy is not only possible but, will provide great benefits in terms of improved patient care, professional satisfaction as well as increased prescription volume. The question many ask is how is this possible when we are so hard-pressed in filling the prescriptions currently at hand.

The answer to that question may not be as apparent, but it has been our experience working with many pharmacists that most can provide extended information and monitoring to those patients most at risk. If this is so, the next question is how can this be accomplished in your busy practice.

There are two principals to follow:

1. Selectivity

Not all persons need information, monitoring or follow-up so we need to be able to identify the patient who does

2. Targeting

All patients are not the same. Some respond to reminders, some simply need to know more.

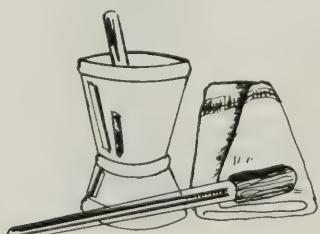
Others need help in scheduling their medicines, or require labels with large print, etc.

We have found in our work at the University of Maryland that a key indicator on which to select the patient who would benefit from your attention is the person who does not get his/her prescription refilled on time. This is especially true for persons who are taking 3 or more prescriptions and who have less than a high school education. If you have a computer, you can have it programmed to identify those persons who have not refilled their prescription on or by the due date so that you can give him/her a further look.

Keying on this small sub-group of your population, a number of things can then be done to identify the problem.

We will deal with the specifics of these programs in a later article, but for those of you who wish more information in the mean time—please call the Office of Community Pharmacy Program, University of Maryland School of Pharmacy and we will see that you receive specific information that will meet your needs.

Dr. Fedder is Associate Professor, Department of Pharmacy Practice and Administrative Science, University of Maryland School of Pharmacy, Research Associate Professor, Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine and Chairman, Maryland Commission on High Blood Pressure and Related Cardiovascular Risk Factors.



A CALL FOR BROWN BAG INFORMATION

I am currently conducting a brown bag review program for senior citizens at Liberty Medical Center as a part of my residency program in geriatric clinical pharmacy at the Un. of MD School of Pharmacy. I have attempted several literature searches to determine what other brown bag programs have contained and how they were developed. In essence, I have found nothing. I know that there are a lot of pharmacists conducting brown bag reviews but there seems to be no information in the literature about them. Therefore, I am putting out a call for brown bag review information.

I would like to establish a mechanism for exchanging information and ideas about different brown bag review programs so that we can learn from one another and as a result improve our own brown bag programs.

I am the consultant clinical pharmacist for the Seniors Get HEP Program at Liberty Medical Center in Baltimore, MD. This is a free health education and promotion program for senior citizens. After an initial assessment by a nurse practitioner, the participant has the opportunity to attend a brown bag review. The brown bag review consists of an individual appointment with me, where the participant brings all prescription and non-prescription medications in their original containers for review. We discuss the mechanism of action and any potential side effects of the individual medications. We discuss any present and past side effects that the participant has experienced, the participant's financial status and any environmental factors such as diet, living conditions, etc. that could affect the participant's medication regimen. I assess the potential for drug-drug interactions, drug-disease state interactions, any factors that could affect the participants' ability to purchase their medications and factors that may impact on the participants' ability to adhere to their medication regimen. I make recommendations to the participant and if necessary to the participant's physician. After the brown bag review, telephone follow-up is done to assess compliance with recommendations and to determine if the medication regimen has changed.

If you have any information about a brown bag program that you are involved with and would like to share that information, please write me at: *Center for the Study of Pharmacy and Therapeutics for the Elderly, % Dr. Peter Lamy, Un. of MD School of Pharmacy, 20 N. Pine St. Baltimore, MD 21201* or call me at 301-328-7338. I would appreciate any information that you might have, and I look forward to establishing an exchange of brown bag review information.

Kathrin C. Kucharski, Pharm.D.
Un. of MD School of Pharmacy

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Community Forum

This month, the Community Forum is devoted to the MPhA Employer/Employee Relations Committee. MPhA encourages all employee and employer pharmacists to write and air their views.

Dudley Demarest, Jr., Pharmacist
Chairman, Employee/Employer Relations

A well known pharmacy journal editor (who just resigned) once told me (about a week ago) that one of the major differences between most medical journals and pharmacy journals was the authorship of many of the letters to the editor and other practice oriented communications. Local medical journals are overflowing with doctors writing and reporting to other doctors about ethical, clinical, procedural, and other practice related topics. Pharmacists don't seem to have the need, desire, or maybe just the time to converse with their fellow practitioners.

I think this lack of public discourse is a fundamental problem in pharmacy today. From disenchantment and disillusionment to philosophical and scientific, this lack of communication creates many of the public, and employee relations problems that our profession sees today.

I hope that this forum will provide space for pharmacists, employees and employers to vent their frustrations, complain about conditions, brag about innovations, and discuss issues. the Employee/Employer Relations Committee will use the forum to report on special projects or concerns that the committee feel need addressing. And since most of you don't seem to have the time to write we have provided appropriate telephone numbers so that pharmacist can vocally convey their concerns to committee members.

The committee has been discussing the need for policy procedure manuals for some time now. Given the liability concerns alone (as they increase daily as pharmacy practices expand into many new areas) its hard to believe that most pharmacies do not have policy procedure manuals, and those that do are usually inadequate. But a policy and procedures manual also makes good business sense. It lets your employees know exactly what's expected of them, what their benefits are, how to handle customer problems, and makes it much easier for new employees (especially fill in pharmacists) to orient themselves to a given pharmacy's routine. We like to hear from employees with any "war" stories and we would greatly appreciate the response of employers and owners who do not have manuals to explain why.

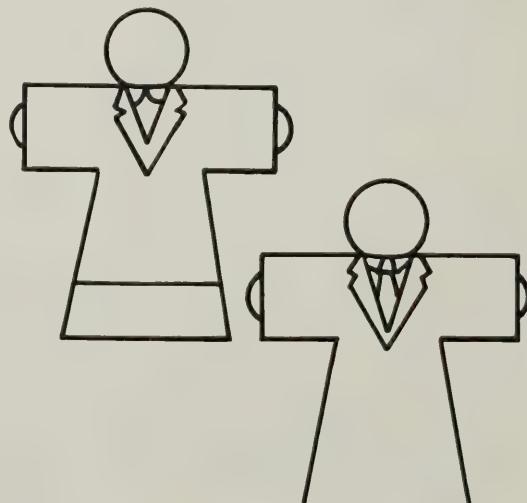
To Whom It May Concern:

The practice of pharmacy is deeply rooted in tradition. Our history is one of firm belief in ethics, honesty, and earnest service to our community. Have you then ever wondered why these same traditions don't shape our business relationships? How many have ever had a written contractual agreement with our employers or employees? Would a set of guidelines improve the standards of employment for pharmacists in the state of Maryland? The members of the Employer/Employer Relations Committee believe a written set of general employment guidelines would benefit all Maryland pharmacists.

The Employer/Employer Relations Committee is drafting the outline for a "Policies and Procedures" Manual for use by all pharmacies in the state of Maryland. Our intent in the design of such a manual is two-fold. First, we hope to establish a set of minimum guidelines in finalizing contractual agreements with prospective employers, whether the agreement be written or verbal. Secondly and perhaps most importantly, a general outline of policies and procedures can serve as a resource to employers seeking to design their own operations manual. We hope that these guidelines will be useful in improving the whole picture of pharmacy employment in Maryland.

The Employer/Employer Relations Committee welcomes your comments and suggestions as we work to draft a set of guidelines which will be adaptable to any type of pharmacy practice setting. Let's stop complaining and start by creating a new tradition of excellence for pharmacy employment in Maryland. Please direct your suggestions to Betty Moses (381-2144/Columbia) or the Committee (727-0746). We're looking forward to hearing from you!

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Betty Moses



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Lovastatin: A New Weapon in the Fight Against Cholesterol

James R. Talley, M.S. and Monica Holiday, R.Ph.

School of Pharmacy

Northeast Louisiana University

Monroe, Louisiana

In the United States, coronary heart disease (CHD) is the leading cause of mortality and accounts for more than 550,000 deaths (1,2). Coronary heart disease can result from atherosclerosis, a progressive condition which eventually leads to narrowing of coronary arteries (2). Due to the insufficient blood flow to the heart, CHD manifests itself in ways ranging from angina pectoris to myocardial infarction. Because CHD is a slow, insidious condition, the first manifestation is often a fatal heart attack (2).

Although the prevalence of CHD in industrialized nations is extremely high, evidence indicates that CHD can be prevented. A number of factors have been identified which increase the possibility of developing CHD. These factors are high blood pressure, smoking, obesity, diabetes mellitus, inactive life style, and high blood cholesterol levels. Several studies have postulated that a reduction in one or a combination of these factors may result in decreased CHD rates (2,3). Almost each of these factors can be attributed to the American lifestyle. The American diet contains excessive calories, fats, and cholesterol (2). A high percentage of Americans are overweight and a large number of Americans are smokers. Studies have shown that people from underdeveloped nations do not have CHD rates nearly as high as Americans. Ironically, when natives of countries with relatively low CHD rates move to the United States and develop the life-style of most Americans, their chance of CHD increases (2).

Even though increased levels of blood cholesterol is not the sole risk factor in developing CHD, it has received a great deal of attention as one of the major causes of atherosclerosis. Cholesterol is not the only lipid containing substance in the bloodstream. However, no other lipid has been shown to contribute to the formation of atherosclerotic plaques to the extent as has cholesterol (4). Atherosclerotic plaques are formed when excessive amounts of plasma LDL deposit in the interstitial spaces and smooth muscle cells of the intimal and medial layers of the artery wall (2,4). As a result, there is considerable narrowing of the vessels that provide coronary blood supply (2).

These statements should not be interpreted that all cholesterol in the bloodstream is detrimental. The

normal cholesterol level is approximately 120 mg/dl. A certain level of cholesterol is necessary for cell growth and steroid hormone synthesis (5). Problems develop when an excess amount of cholesterol is present in the bloodstream (2). Cholesterol is transported in the blood by four major categories of plasma lipoproteins (4). Chylomicrons transport dietary triglyceride and cholesterol. Very low density lipoproteins (VLDL) are the principal carriers of hepatically synthesized triglycerides. Thus, very low density lipoproteins (VLDL) primarily transport triglycerides that have been synthesized in the liver. The remaining two categories of lipoproteins function primarily in the transport of endogenous cholesterol. These categories are low density lipoproteins (LDL), and high density lipoproteins (HDL). Approximately 70% of total plasma cholesterol is transported by LDL (4). Because of this fact, overabundant amounts of LDL are implicated in the development of atherosclerosis.

As stated earlier, LDL is necessary to supply the body's cells with cholesterol. Excessive amounts of LDL may result from overingestion of fats in the diet. Low density lipoprotein levels may also be excessive due to a genetic deficiency in LDL receptors (4). According to Goldstein and Brown, correctly functioning LD receptors supply cells with adequate amounts of cholesterol without allowing levels high enough to precipitate atherosclerosis (4). The existence of high affinity LDL receptors allows the body to maintain plasma LDL levels below the threshold range for atherosclerosis and at the same time supply cells with adequate amounts of cholesterol. Elevated levels of LDL are noted in patients with heterozygous familial hypercholesterolemia, who have about 40% to 50% of the necessary LDL receptors, and in patients with homozygous familial hypercholesterolemia, who lack LDL receptors. Patients in the latter group usually develop myocardial infarctions before age 20 (4).

Unlike LDL, increased levels of high density lipoprotein (HDL) are correlated with a decrease in the formation of atherosclerotic plaques (6). Information from the Framingham Study has indicated that the incidence rate of coronary heart disease was eight times higher in patients with HDL levels below 35 mg/dl than in patients with HDL levels of 65 mg/dl or more. According

to Dr. William P. Castelli of the Framingham heart study, the higher the HDL, the lower the rate of subsequent heart disease. Dr. Castelli has stated that HDL initiates the transport of cholesterol back to the liver which represents about 95% of cholesterol per day that patients excrete. Thus, higher HDL levels could result in lower total body cholesterol.

The Lipid Research Clinics Coronary Primary Prevention Trials found that increases in HDL levels in patients treated with cholestyramine provided an additional decrease in CHD risk in conjunction with decreased LDL levels (7). Since a decrease in LDL levels and an increase in HDL levels are associated with a decrease in CHD risk, effective preventive therapy in CHD should employ these principles.

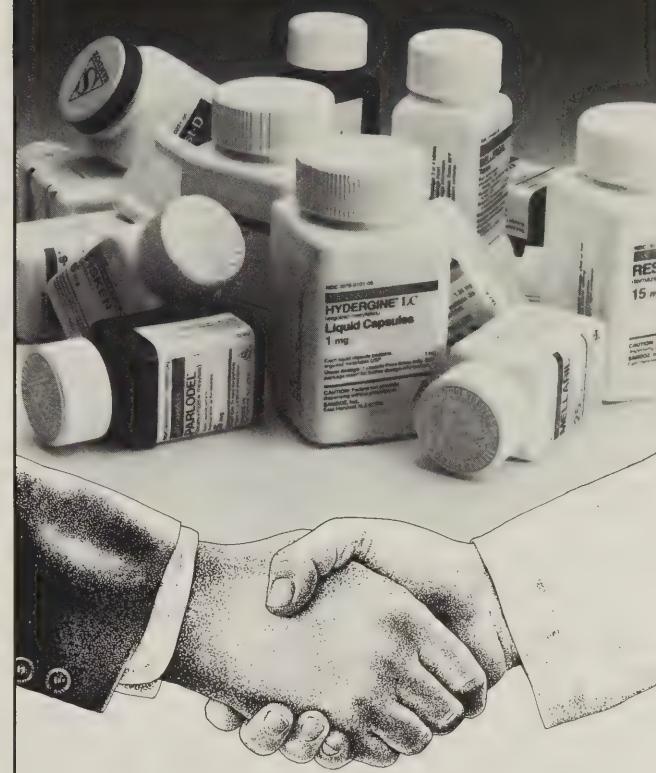
Hypercholesterolemia is divided into two groups according to the National Heart Lung and Blood Institute and the National Institutes of Health Office of Applications (2). Moderate risk hypercholesterolemia is denoted as greater than 200 mg of cholesterol per deciliter of blood in patients 20 to 29 years of age, greater than 220 mg/dl in patients 30 to 39 years old, and greater than 240 mg/dl in patients 40 years old or older. High risk hypercholesterolemia is described as cholesterol levels greater than 220 mg/dl in 20 to 29 year olds, greater than 240 mg/dl in 30 to 39 year olds, and greater than 260 mg/dl in patients 40 years old or older. Both moderate and high risk hypercholesterolemia should be treated.

Although there are drugs available that will lower serum cholesterol levels, these drugs are used only after a diet that reduces calories, fats, and cholesterol has proven insufficient (2). In the treatment of hypercholesterolemia, the Blood Cholesterol Consensus Conference recommends that no more than 250 mg to 300 mg of cholesterol be consumed per day with a fat intake of about 30% to total caloric intake. Saturated fats should compose no more than 10% of daily calories. If this diet is inadequate in arriving at a normal blood cholesterol level, total fat intake should be decreased to 20% to 25% of calories with saturated fats comprising 6% to 8% of total calories. No more than 150 mg to 200 mg of dietary cholesterol should be consumed per day (2). An increase in the amount of physical activity may also be beneficial in lowering serum cholesterol levels.

A cholesterol restricted diet is the first step in lowering blood cholesterol, but diets that lower cholesterol by substantial amounts are unpalatable and consequently have a low degree of compliance. Low cholesterol diets appetizing enough to be tolerated by most patients only reduce cholesterol levels by about 10% (8,9).

Only after a serious effort at decreasing serum cholesterol by diet has proven ineffective should drug therapy be utilized. Fortunately, medications are available to potentiate decreases in cholesterol. The most common antilipidemic agents in use today are the bile

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acid sequestrants (cholestyramine and colestipol), probucol, nicotinic acid acid, dextrothyroxine, and the fibrac acids (clofibrate and gemfibrozil). These drugs are listed in Table 1. A number of hypercholesterolemic patients are not willing to utilize the aforementioned agents because of their side effects, expense, or unpalatability.

TABLE 1
Antilipidemic Agents

| | Trade Name | Company |
|-------------------------------|------------|--------------|
| <i>Bile Acid Sequestrants</i> | | |
| Cholestyramine | Questran | Mead Johnson |
| Colestipol | Colestid | UpJohn |
| <i>Fibrac Acids</i> | | |
| Clofibrate | Atromid-S | Ayerst |
| Gemfibrozil | Lopid | Parke Davis |
| <i>Other Agents</i> | | |
| Dextrothyroxine | Choloxin | Flint |
| Nicotinic Acid (Niacin) | various | various |
| Probucol | Lorelco | Merrell Dow |
| Lovastatin (Mevinolin) | Mevacor | MSD |

Bile Acid Sequestrants: Cholesterol is the major precursor of bile acids (10). Bile acid sequestrants function by forming an insoluble complex with bile acids in the intestine. This complex is subsequently excreted in the feces (10). Drugs in this category are cholestyramine (Questran by Mead Johnson) and colestipol HCl (Colestid by UpJohn). These resins are available in the form of powders which are mixed in a liquid drank. The recommended daily dose of cholestyramine is four grams, one to six times daily. For colestipol, the recommended daily dose is fifteen to thirty grams, two to four times daily. The bile acid sequestrants decrease serum levels of LDL and either increases or leave unchanged serum VLDL levels. Constipation and aggravation of hemorrhoids are common in patients using these drugs.

Probucol: Probucol (Lorelco by Merrell Dow) exhibits its antihyperlipidemic effect by increasing the catabolic rate of LDL. Thus, cholesterol synthesis, dietary cholesterol absorption, and cholesterol in HDL fractions are also decreased by probucol. The recommended dosage of probucol is 500 mg with morning and evening meals. Diarrhea is a problem for about 10% of the patients using probucol.

Nicotinic Acid: Nicotinic acid (niacin) therapy results in a decrease in LDL synthesis by decreasing the synthesis of VLDL. Low density lipoproteins are a product of the catabolism of VLDL. High density lipoprotein is increased with niacin therapy. Required doses of niacin range from one or two grams daily. The most common side effect is cutaneous flushing; primarily of the face, neck, and ears.

Dextrothyroxine: Dextrothyroxine (Choloxin by Flint) results in a reduction of serum cholesterol and LDL levels in hyperlipidemic patients. This drug stimulates the liver to increase cholesterol catabolism and in-

creases the excretion of cholesterol and degradation products by the biliary system into the feces.

Fibrac Acids: The antihyperlipidemic agents known as the fibrac acids are clofibrate (Atromid-S by Ayerst) and gemfibrozil (Lopid by Parke Davis). Both clofibrate and gemfibrozil lower serum triglyceride and VLDL levels. Neither agent has a great effect on LDL levels. However, gemfibrozil may increase HDL levels. Clofibrate is usually administered, two grams daily in divided doses. The major side effect associated with this drug is nausea. The recommended dose of gemfibrozil is 120 mg/day in two divided doses. Common side effects associated with this drug are abdominal pain, epigastric pain, and diarrhea.

Lovastatin: The previously discussed drugs are only correctly utilized in a few patients because of their expense and side effects. Fortunately, a new class of antihyperlipidemic agents has been developed. Lovastatin (Mevacor by Merck Sharp & Dohme) is one such drug. It is available in 20 mg tablets with a recommended starting dose of 20 mg once daily with the evening meal. The recommended dosage range is 20 mg to 80 mg daily in single or divided doses. Mevacor is 20 mg to 80 mg daily in single or divided doses. Mevacor received FDA approval in early September 1987, and was available to patients by the end of the month.

Lovastatin (formerly mevinolin) was isolated from a strain of *Aspergillus terreus* (10). In the fight against hypercholesterolemia, this agent reduces LDL levels and increases HDL levels. Three-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) is converted to mevalonate by the enzyme HMG-CoA reductase (10,11). Mevalonate is essential in the formation of cholesterol. In vivo, mevinolin is hydrolyzed to mevinolinic acid (12,13). Mevinolinic acid is a potent inhibitor of HMG-CoA reductase. Accordingly, cholesterol synthesis is reduced because lovastatin acts as an inhibitor of HMG-CoA reductase and subsequently interrupts the biosynthesis of cholesterol. Therapeutic doses of lovastatin do not produce a complete inhibition of HMG-CoA. Therefore, adequate amounts of cholesterol are still available for normal cell growth and steroidogenesis (12).

As stated earlier, increased LDL levels may be due to a deficiency in LDL receptors. Located on the surface of non-hepatic cells, these receptors are instruments by which the cell binds plasma LDL required for growth (4). Lovastatin's mechanism of action may entail an induction of LDL receptors (12,13). An induction of LDL receptors help to eliminate LDL in the bloodstream while inhibition of HMG-CoA reductase decreases its production.

The relative safety and effectiveness of mevinolin were demonstrated in several clinical trials. One such trial was a double-blind, placebo controlled study involving 50 healthy men (11). For a period of four weeks, doses as small as 6.25 mg and as large as 50 mg were administered twice daily. At the end of treatment,

total serum cholesterol decreased 23% to 27% while LDL levels decreased 35% to 45%. The highest dose did not demonstrate a significantly larger decrease in cholesterol than the smallest dose. Only one subject was withdrawn from the study because of adverse effects. Although a dosage schedule of 25 mg once daily did result in a decrease in cholesterol levels, the decrease was not as substantial as those from the use of 6.25 mg and 12.5 mg twice daily.

Nonfamilial hypercholesterolemia is an elevated cholesterol level which is not due to genetic factors. A double-blind, placebo controlled study of 101 nonfamilial primary hypercholesterolemia patients was performed to examine the safety and effectiveness of lovastatin in these patients (8). Treatment was studied over an 18 week period. Doses of 10 mg to 80 mg per day were administered as single or divided doses. Total cholesterol and LDL levels decreased substantially in all groups. The 40 mg bid group showed the greatest decrease in total cholesterol levels. The mean reduction was 32% in these patients. This group also demonstrated the sharpest decrease in LDL (39%). No patient had to be withdrawn from the study and no serious adverse effects due to lovastatin were reported.

Familial hypercholesterolemia is a result of genetic deficiencies of LDL receptors. A double-blind, randomized crossover, placebo controlled study in 24 patients with familial or nonfamilial hyperlipoproteinemia was performed (14). Mevinolin lowered total cholesterol by 24% to 29% and LDL by 31% to 34%. The concentration of HDL was increased 16% compared with the placebo. The nonfamilial hypercholesterolemia patients experienced a larger decrease in total cholesterol levels than did the familial patients. However, when results were compared by percentages, decreases in LDL for both groups were similar. No serious toxicity due to treatment with mevinolin was observed.

Overall, less than 1% of patients were discontinued from controlled clinical trials due to lovastatin related adverse effects (12). The most common adverse effects were gastrointestinal and included: constipation, diarrhea, dyspepsia, flatus, abdominal pain and cramps, heartburn, and nausea. The incidence of these effects were usually lower with lovastatin as compared to other antilipidemic agents. Headache and rash were other major side effects reported.

A number of patients that were eliminated from studies due to adverse effects developed substantial increases in serum transaminases. Therefore, it is recommended that liver function tests be performed every four to six weeks during the first 15 months of lovastatin therapy and periodically thereafter (12). Accordingly, lovastatin should be used cautiously in heavy alcohol consumers.

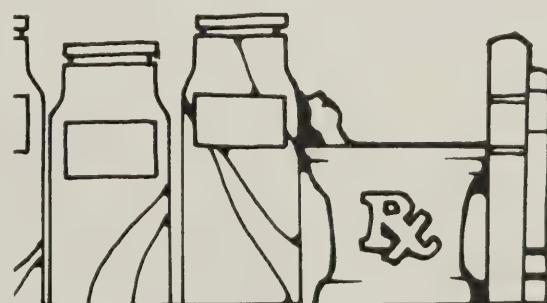
Clinical trials also showed a high incidence of lens opacity development in patients treated with lovastatin. There were no decreases in visual acuity reported in these patients. It is recommended that all patients

treated with lovastatin have slit lamp eye examinations at least every year (12).

Although several clinical studies showed the substantial antilipidemic effect of lovastatin, it should not be considered a miracle drug. Patients utilizing lovastatin must still comply with low cholesterol diets in order to get adequate results. Nevertheless, because of its relatively simple dosing schedule, relatively low incidence of side effects, and its appreciable decrease in serum cholesterol levels, lovastatin may become an effective weapon in the fight against cholesterol.

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For a Society experiencing a 23 percent growth rate in 1988, it was a landmark when Sheryl Brehm, staff pharmacist at the Spencer Municipal Hospital in Spencer, Iowa, joined in mid-March, tipping the membership scale over the 3,000. This high growth rate follows a 13 percent increase in member enrollment in 1987 and a 17 percent rate the year before.

By participating in Society teleconferencing programs, Midyear Conferences and Annual Meetings, members earn continuing education credits and stay abreast of the profession's latest advancements. Attendance at the 1987 fall Annual Meeting created a new Society's record of 2,100 registrants, up by more than 65 percent from 1986 figures.

To meet the needs of its growing membership, the Society's Washington, D.C., headquarter's staff has doubled in size during 1987. Long-term care and consultant pharmacists focus their efforts on ensuring that patients continue receiving the highest quality, most cost-efficient and appropriate pharmaceutical services available.

NATIONAL PATIENT COUNSELING COMPETITION

Joy Meier of Philadelphia College of Pharmacy and Science is the winner of the 1988 USP/APhA Academy of Students of Pharmacy National Patient Counseling Competition. The competition was held at the 135th Annual Meeting of the APhA, March 12-15, 1988, in Atlanta, Georgia. The three runners-up were Cheryl Gauthier, Xavier University of Louisiana; Robert Wockack, Wayne State University; and Lawrence Carey, Temple University.

After months of competition at the schools of pharmacy involving over 1000 students, sixty ASP chapters sent their winners to this fourth national competition. Each national participant received an engraved pen and pencil set and a commemorative T-shirt for participating in the National Competition, which was sponsored by ASP and the United States Pharmacopeial Convention, Inc.

Ms. Meier was awarded an engraved leatherbound, gilt-edged collector's edition of the *United States Pharmacopeia/National Formulary (USP/NF)* as well as a \$600 honorarium. The three runners-up received \$400, \$300, and \$200 honoraria respectively for their outstanding patient counseling.

The six other finalists in the National Patient Counseling Competition were Mona Cochran, Auburn University; Paula Morgan, University of Colorado; Patrick O'Brien, University of Arizona; Stephanie Parks, Washington State University; Noel Wilkin, University of Maryland; Leslie Woodward, University of Utah. All the finalists were awarded editions of the *USP/NF* for their efforts.



Noel Wilkin, from the University of Maryland School of Pharmacy made it to the final rounds of the USP Patient Counseling Competition.

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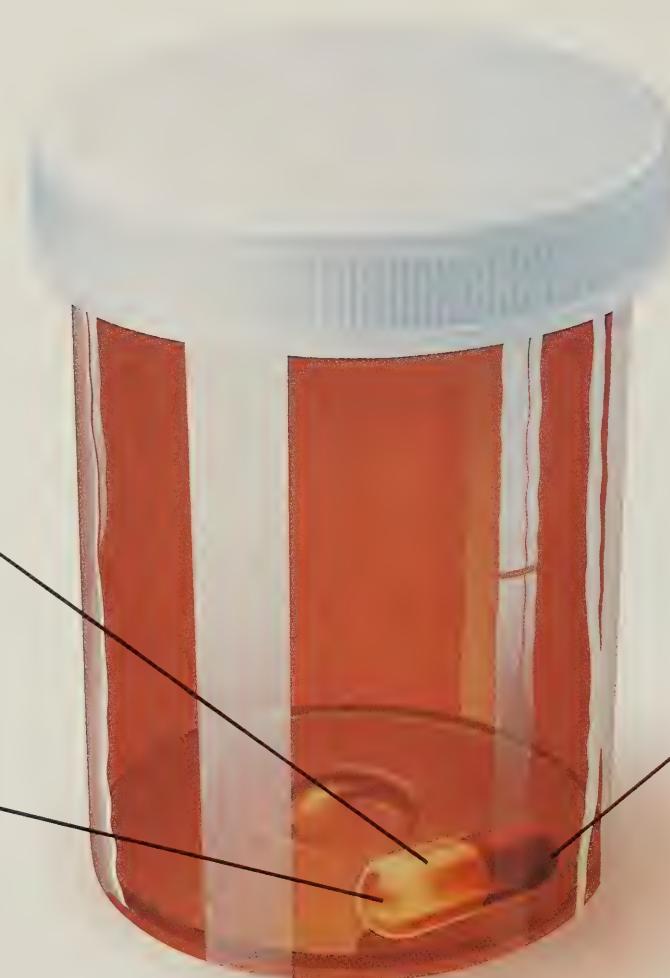
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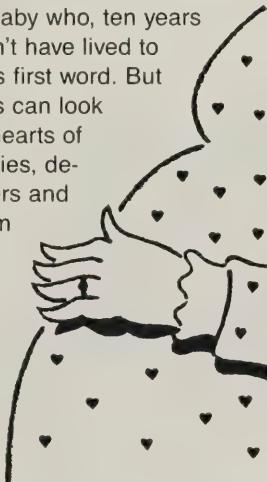


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Hypertension - What, Why and How

High blood pressure, also known as hypertension: What is it? Why all the commotion about it? And, how can it be controlled? To better understand high blood pressure let's look at normal blood pressure.

Blood pressure is the force placed upon blood vessels, such as arteries and capillaries, by the blood they contain. This force is measured by a blood pressure cuff (sphygmomanometer) placed around an arm or thigh. Cuff readings contain two parts identifying distinct pressures. The first reading is called the systolic blood pressure and is a measure of the force on blood vessels when the heart is at work (during contraction). When the heart relaxes a second pressure, the diastolic pressure, is measured. Diastolic pressure is of most concern because it represents the minimum force exerted on these vessels.

Normal blood pressure (systolic of 120 and diastolic 80) can be thought of as the average blood pressure of healthy people. However, your blood pressure may be slightly elevated or decreased as compared to the average person without being referred to as "high" or "low" blood pressure. It is generally accepted that blood pressure is high when it consistently registers 160/95 or more, measured over a period of days or weeks.

Researchers are not completely certain of the exact cause of hypertension. However, several theories exist that

identify factors contributing to the development of high blood pressure. These factors include: one's lifestyle; the amount of daily stress encountered; dietary habits; the amount of physical exercise; smoking; family history; sex; and race. More concrete, yet relatively infrequent, causes of hypertension are physical malfunctions such as kidney problems or hormonal imbalances.

Sustained high blood pressure can be dangerous because it can damage blood vessels. To understand how this happens think of a water balloon. The balloon will hold only a certain amount of water before it bursts. Damage like this in the kidneys, eyes, heart or brain may lead to stroke, heart attack, blindness or death.

High blood pressure is known as "the silent killer" because there are usually no noticeable symptoms. Detection can only occur during a thorough physical examination by your physician.

Control of hypertension is a life-long endeavor. Your treatment can include altering your diet, losing weight, getting more exercise, taking medication or a combination of these. It is important to stress, however, that losing weight and increasing your exercise should be undertaken only under the close supervision of your doctor.

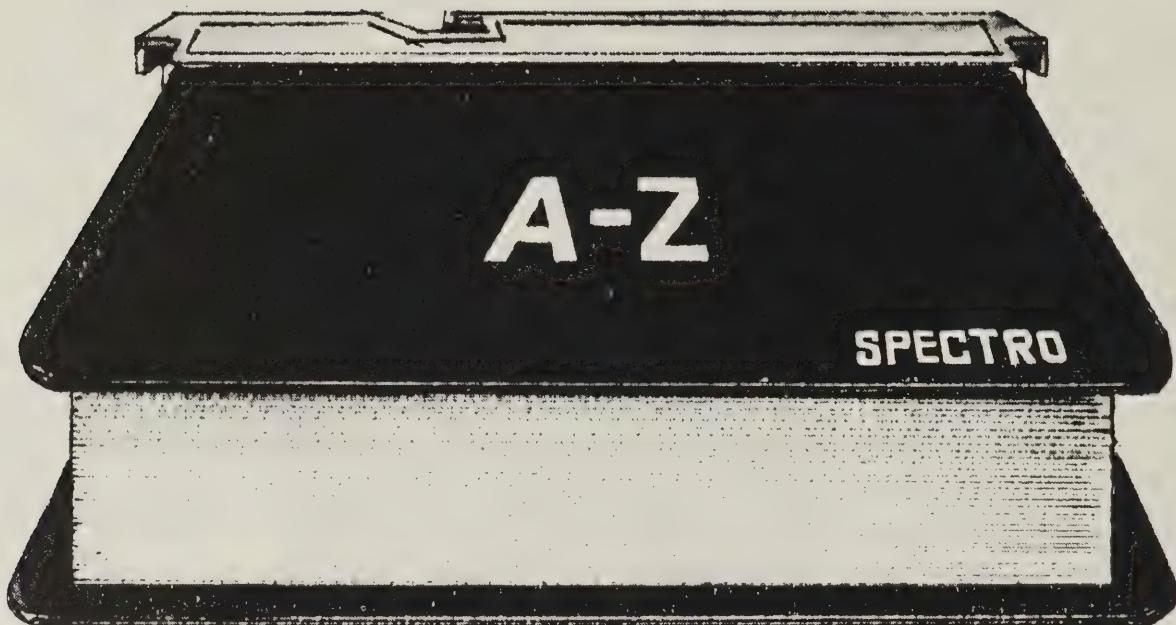
May is High Blood Pressure Month. Make a special effort to ask your doctor or pharmacist about this disease. It's For Your Good Health!

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High Blood Pressure Update

Definition

High blood pressure in adults is defined as two or more blood pressure measurements averaging 140 mm Hg or higher systolic or 90 mm Hg or higher diastolic, taken on three separate occasions.

Morbidity and Mortality

Uncontrolled high blood pressure can lead to stroke, heart attack, coronary heart disease, congestive heart failure, kidney failure, and arteriosclerosis. High blood pressure contributes directly or indirectly to about 1 million deaths a year.

High blood pressure is the major factor contributing to the 500,000 strokes and 155,000 stroke deaths that occur in the United States every year. High blood pressure also contributes to the 1.5 million heart attacks and 567,000 heart attack deaths in our country every year. Heart disease is the leading cause of death for American men and women of all races.

Prevalence Data

Approximately 58 million adult Americans, or more than one in four, have high blood pressure. Anyone can have high blood pressure, but it is more common among older Americans. The prevalence of hypertension also differs by sex and race, as depicted below.

**Hypertension and Prevalence Rates by Sex, Race, and Age
Civilian, Noninstitutionalized Population
(Ages 18-74 Years) 1976-80**

| AGE IN YEARS | MALES | | | FEMALES | | | TOTAL | | |
|--------------|------------|------------|---------------|------------|------------|---------------|------------|------------|---------------|
| | Whites (%) | Blacks (%) | All Races (%) | Whites (%) | Blacks (%) | All Races (%) | Whites (%) | Blacks (%) | All Races (%) |
| 18-74 | 32.6 | 37.9 | 33.0 | 25.3 | 38.6 | 26.8 | 28.8 | 38.2 | 29.8 |
| 18-24 | 16.2 | 10.9 | 15.2 | 2.3 | 9.6 | 3.5 | 9.1 | 10.2 | 9.2 |
| 25-34 | 21.1 | 23.2 | 20.9 | 5.7 | 15.3 | 6.9 | 13.3 | 18.8 | 13.7 |
| 35-44 | 26.4 | 44.2 | 28.4 | 16.6 | 37.0 | 19.3 | 21.3 | 40.1 | 23.7 |
| 45-54 | 42.6 | 55.2 | 43.7 | 36.3 | 67.4 | 39.1 | 39.4 | 61.7 | 41.3 |
| 55-64 | 51.4 | 66.3 | 52.6 | 50.0 | 74.3 | 52.6 | 50.6 | 70.7 | 52.6 |
| 65-74 | 59.2 | 67.1 | 60.2 | 66.2 | 82.9 | 67.5 | 63.1 | 76.1 | 64.3 |

Source: NHANES II.

*Defined as the average of three blood pressure measures \geq 140/90 mm Hg on a single occasion or reported taking of antihypertensive medication.



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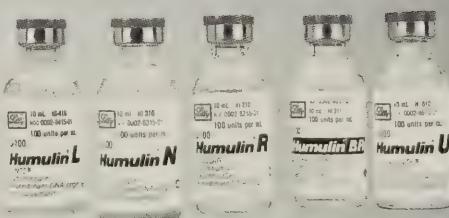
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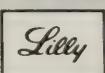
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At an early morning meeting at the APhA Convention, Dr. Fedder, Brian Sanderoff, and President Lee Ahlstrom discuss the proposed resolutions.



MPhA made a strong showing at the APhA Convention. Shown here are House Speaker Brian Sanderoff, Trustee Kathleen Gauthier, President Lee Ahlstrom, and member Kathy Parker.



More than 15 University of MD students attended the convention in Atlanta. Mike Fossler, president of Maryland's ASP chapter and Mari Kim, fifth year student, "cleaned up" in the Exhibit Hall.



Lee Ahlstrom, Toni Ushkowitz, and Maddy Feinberg visit at the Parke-Davis Elder Care booth.

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THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALITMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

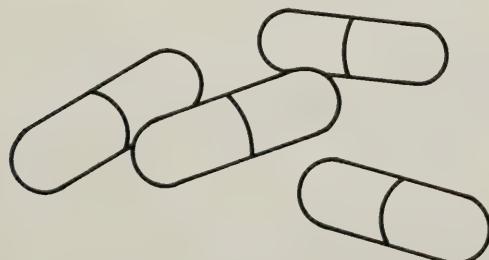
LAMBDA KAPPA SIGMA sorority is planning its 75th Anniversary, August 2-6, 1988 at the Copley Plaza Hotel in Boston. All LKS sisters are encouraged to come and celebrate the future of LKS and women in pharmacy. For details, contact Mary Greer at Lambda Kappa Sigma, P.O. Box 981, Claremont, OK 74018.

SPECIAL SEMINAR PLANNED on "Teaching People with Low Literacy Skills: A Workshop for Health Professionals" for April 14, 1988, 8:30 a.m. to 4:00 p.m. at the Lord Baltimore Hotel. For registration information, contact Phyllis Wood, R.N., M.P.H. at 532-3838.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.



Next Month . . . Arthritis

calendar



- May 19 (Thurs.)—Alumni Association Graduation Banquet Martin Eudowood
May 20 (Fri.)—Graduation—Class of 1988 School of Pharmacy
June 5 (Sun.)—CECC—Substance Abuse Among Pharmacy Staff
June 5-9—ASHP Annual Meeting—San Francisco
June 12 (Sun.)—AZO Installation Dinner Meeting
June 19-23—MPhA CONVENTION—SHERATON OCEAN CITY—RESERVE YOUR SPOT IN THE SUN
Oct. 21 (Fri.)—MSHP Annual Seminar—Sheraton Ocean City, Md.



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4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
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Maryland ^{The} *Pharmacist*

VOL. 64

JUNE, 1988

NO. 6



The Pharmacist and Arthritis

Commentary

It has been my pleasure to serve as your President this past year. This has been a time of growth and challenge.

The Prescription Network has matured and demonstrated its ability to supply a variety of services to providers of health care. The joint promotion between MPhA, USP and WBAL-TV of the "About your Medicines" book published by USP, reminded millions of television viewers that their local community pharmacist is the best source for information about the uses and side effects of medications.

Our first legislative breakfast in Annapolis was a tremendous success, attended not only by Governor William D. Schaefer and Lt. Governor Melvin Steinberg, but also by many Delegates, Senators and pharmacists from around the state. This breakfast created a forum for one-on-one discussions between pharmacists and their elected representatives. Governor Schaefer stressed the importance of creating a dialogue with these officials so that they know both sides of the issue.

The legislative session was almost a non-event for pharmacy this year. Our principal bill, the mandating of equal co-payment for traditional community pharmacy service and mail-order options, was referred to summer study, where with education of key people to the issues, we anticipate stronger support in the next session. Although we were not successful in producing new legislation, we did emerge without any bills damaging to pharmacy being enacted.

MPhA, along with our political allies, as successful in defeating an increase in the co-pays on medical assistance prescriptions. This would have had a tremendous economic impact on pharmacy in the state because, if the medical assistance patient is unable to pay the deductible amount, pharmacies cannot deny service and any shortfall comes directly from pharmacy reimbursement.

During the past year, we lost the services of our Executive Director, David Banta, to a national organization. While this was a setback to lose such an experienced, capable and well-liked leader, it is a tribute to the officers, staff and volunteers of MPhA that we not only maintained the status quo, but actually expanded our scope of activities and established new and innovative programs during his absence. Much appreciation and thanks go to Beverly Litsinger, Dawn Ranger, Dave Miller, Mel Rubin and many others in the office who helped this to happen.

I would like to give special thanks to the Selection Committee who conducted dozens of interviews, met on weekends and at all hours of the day and night to choose the best candidate from a large pool of highly qualified applicants. Our new Executive Director, Greg Wood, has the background, experience and qualifications necessary to assist and guide our organization into the future.

I leave office with a good feeling about our new leadership and the course along which we are moving. I know the next few years will only make our Association stronger and more successful.

Lee Ahlstrom

President

Continuing Education

DIARRHEA AND ITS TREATMENT

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION



by J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

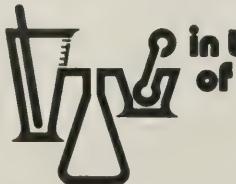
and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. provide information on the causes and treatment of diarrhea; and
2. discuss the recommendations of the FDA/OTC committee that reviewed OTC antidiarrheal drug product ingredients.



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of pharmacy**

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Objectives

At the conclusion of this lesson, participants will be able to:

1. demonstrate an understanding of major etiologic factors associated with the diarrheal process;
2. select from a list of drugs those that are safe and effective OTC anti-diarrheal product ingredients;
3. list warnings and precautions, pharmacologic action and major drug interactions associated with OTC antidiarrheal drug products; and
4. identify specific points of patient advice about prevention and treatment of diarrhea.

Diarrhea is difficult to define. Some individuals may define it as three bowel movements a day, while others consider this to be normal.

Generally, diarrhea can be defined as an abnormally frequent passage of stools, high in water content, that usually occurs without identifiable cause.

The key phrase in this definition is the "high water content" of the stools. The body has efficient mechanisms for conserving fluids. The normal daily fecal excretion is four to six ounces, of which 60 to 95 percent is water.

Usual fluid intake for most adults exceeds 2 liters per day, and more than 7 liters of fluid are secreted into the alimentary canal via saliva, gastric and intestinal juices and other biosecretions. In spite of this, only 80 to 120 ml of water are excreted. Merely doubling this quantity can constitute forceful, watery stools and diarrhea.

Any intestinal condition that interferes with electrolyte and/or water absorption/reabsorption may result in diarrhea.

Mild, self-limiting diarrhea that is

not accompanied by fever or blood in the stools is considered to be self-treatable. Prolonged diarrhea can be serious.

Diarrhea is a major health problem worldwide. In underdeveloped countries where sanitation control is poor and dietary deficiency is widespread, diarrhea is a leading cause of debility and death.

While less deadly in the U.S., diarrhea is a primary cause of serious illness. Approximately 700 persons die each year of complications associated with it.

Acute diarrhea is generally short-lived and self-remedied. Chronic diarrhea can persist and cause significant disturbances in fluid and electrolyte balance.

Diarrhea results from excessive secretion by intestinal cells, malfunction of the absorption-transport systems, increased osmotic pressure in the gastrointestinal (G.I.) tract, or improper intestinal wall motility. It may result from either hypermotility or hypomotility of the intestine.

Diarrhea is a symptom. Treatment of prolonged diarrhea should be aimed at its cause.

Acute Versus Chronic Diarrhea

The most probable cause of **acute diarrhea** is an attempt by the alimentary tract to rid itself of irritating or toxic substances. It is self-limiting, usually lasting from 12 to 72 hours. Acute diarrhea may be of toxic, infectious, or dietary origin, or it may result from some other short-term illness.

Substances responsible for the toxic variety include any item that is unnatural to the G.I. tract, which is able to irritate the delicate mucosal lining of the intestinal wall. Common infectious agents include *Escherichia coli*, *salmonellae*, *shigellae* and *rotavirus*.

The normal intestinal microbial flora remains remarkably constant, and is able to resist invasion by other bacterial species present. Therefore, any event that interrupts the normal activity and balance of the intestinal flora is likely to precipitate an episode of diarrhea, possibly by increasing the susceptibility for infections with invading pathogens.

At times, microorganisms normally present in the healthy intestine in their nonpathogenic forms may become pathogenic and cause local or systemic infections. *E. coli* is an example of such an organism.

Travelers' diarrhea is one common cause of acute diarrhea resulting from an altered intestinal flora. It may result when an individual experiences a different climate, food, or fluid intake. It usually develops within 2 to 10 days.

The individual so affected may experience 10 to 20 bowel movements a day, accompanied by severe abdominal cramping, chills, fever, nausea and vomiting. Some experts believe that approximately 75 percent of these episodes are caused by pathogenic strains of *E. coli*. Besides water, fresh fruits, and raw vegetables, drugs such as antacids which increase the alkalinity of the G.I. tract favor survival of pathogenic organisms.

Non-carbonated bottled drinks are more suspect of carrying the bacteria responsible for diarrhea, than carbonated beverages. This may be due to the lower pH in carbonated drinks which makes them less compatible for organism survival.

Another form of acute disease is **antibiotic-induced diarrhea**. Virtually all antibiotics are capable of inducing diarrhea, but this problem is most often encountered with broad spectrum ones such as tetracyclines, ampicillin and clindamycin.

Antibiotics disrupt the normal intestinal flora so that foodstuffs are not properly digested and absorbed. This then leads to increased intestinal water content and diarrhea. There may also be an overgrowth of antibiotic-resistant bacterial or fungal strains that produce the condition.

Treatment of severe antibiotic-induced diarrhea (i.e., pseudomembranous colitis) requires physician supervision and oral vancomycin,

followed by a bile sequestrant agent such as Colestid or Questran. OTC antidiarrheal products are of little use, and prescription antiperistaltic products should be avoided. By reducing the propulsion of the toxic metabolites produced by bacteria which are causing the diarrhea, the disease is likely to worsen.

Chronic diarrhea is defined as diarrhea that does not subside when the toxic or irritating substance is removed from the G.I. tract.

To differentiate it from the acute form, chronic diarrhea generally persists longer than three days, and is usually the result of multiple etiological factors. It is difficult to diagnose and treat effectively. A major complication is dehydration.

Most often, chronic diarrhea is a symptom of a more serious organic disease, such as colorectal cancer (note that one of the warning signs of cancer is "any change in normal bowel habits"). Chronic ulcerative colitis, amoebic dysentery, tuberculosis, enteritis and sprue are other causes.

Treatment of Diarrhea

The treatment of diarrhea is divided into three basic categories: supportive, symptomatic, and specific. **Supportive therapy** involves replacing lost fluids and electrolytes. In severe cases of dehydration, intravenous fluids must replace the specific electrolytes lost. Oral therapy is generally less specific with a more standardized formula used.

Symptomatic therapy involves drug use. These agents do not alter the underlying pathophysiology, nor do they correct the electrolyte or fluid loss. They can help, however, to reduce these losses and make the patient more comfortable.

Specific therapy is directed at treating the underlying condition. Examples of specific therapy include the use of appropriate antibiotics, treatment of metabolic disorders, replacement of pancreatic enzymes, and/or discontinuance of diarrhea-causing drugs.

Important Non-Drug Therapy. Before recommending a particular treatment or product, the duration of diarrhea, person's age and general

health, other symptoms such as fever, and any medications being taken should be determined. This will help him determine the potential seriousness of the condition and the possible need for physician referral.

Adequate fluid intake is absolutely necessary to prevent dehydration. Since excessive fluids are lost rapidly, persons with diarrhea should consume as much as possible.

Very young and very old patients are especially susceptible to dehydration. As long as the patient is not nauseated, and is only mildly dehydrated, oral replacement with water is usually adequate. With moderate dehydration, electrolyte replacement may be needed. A general rule of thumb is to take in electrolytes during any bout of diarrhea that persists beyond 12 hours.

One "home remedy" for providing essential electrolytes is a solution of one quart of tap water, two tablespoons of Karo syrup or sugar, one-half teaspoon of salt, one-fourth teaspoon of salt substitute (potassium chloride), and one-half teaspoon of bicarbonate of soda. Ingredients should be measured as accurately as possible. Eight ounces of this mixture every two hours should replace fluid and electrolyte loss.

Commercial products such as Gator-Aid will also serve the purpose, and are more convenient. Specific OTC electrolyte solutions are also available (Table 1).

The affected individual should continue to consume soft foods such as broths, soups and gelatin which can be absorbed across the intestinal mucosa without difficulty. Milk products should be avoided because intestinal lactase may be deficient during diarrhea. Solid foods or large quantities of foods may further irritate the intestine and delay alleviating the disorder.

TABLE 1

| OTC Oral Electrolyte Mixtures | |
|-------------------------------|--------|
| Product | Form |
| Gastrolyte | Powder |
| Hydra-Lyte | Powder |
| Infalyte | Powder |
| Lytren | Liquid |
| Pedialyte | Liquid |
| Pedialyte RS | Liquid |
| Resol | Liquid |

TABLE 2

| Drug Ingredients Claimed To Have Antidiarrheal Activity | |
|---|-------------------------|
| Alumina powder | Kaolin |
| Atropine | Lactobacilli |
| Attapulgite* | Opium derivatives |
| Bismuth subnitrate | Paregoric |
| Bismuth subsalicylate | Pectin |
| Calcium carbonate | Phenyl salicylate |
| Calcium hydroxide | Polycarbophil* |
| Carboxymethylcellulose | Potassium carbonate** |
| Charcoal | Rhubarb fluid extract** |
| Glycine** | Scopolamine** |
| Homatropine | Zinc phenol sulfonate** |
| Hyoscyamine | |

*As of 4/86, FDA had found sufficient evidence of proof of efficacy and safety.

**Ingredients are either unsafe or ineffective for OTC use as antidiarrheals.

When to Avoid Self-Medication of Diarrhea

Some persons with diarrhea should be referred to a physician rather than self-medicate their condition. **Children under the age of 3** should be referred because their fluid/tissue ratio is low to start. Consequently, whenever relatively small quantities of fluid are lost through diarrhea, severe dehydration may result.

FDA believes that this is of sufficient importance to require the following warning on OTC antidiarrheal products: "Do not use this product in children under 3, or longer than 2 days in children above 3, or in the presence of fever, except on the advice of a doctor."

Adults above age 60, or those with poor health, should be referred to a physician. Additionally, any individual with a **chronic disease** such as asthma, diabetes, or heart disorder should be referred to a physician, as should **pregnant women**. In each of these instances, a loss of electrolytes may lead to serious complications.

OTC Antidiarrheal Drugs

Short-term uncomplicated diarrhea is self-treatable in most persons. Many drugs purported to relieve diarrhea have been used through the years. These include the adsorbents, belladonna alkaloids, lactobacillus organisms, opium derivatives, and astringents (Table 2).

During its extensive review of the available data on OTC antidiarrheal drugs, an FDA panel of experts found little conclusive evidence of effectiveness for most of these agents. The only three that were classed as Category I (safe and effect-

ive) ingredients were attapulgite, opium derivatives, and polycarbophil.

By the time the advisory panel submitted its report (mid-1970's), paregoric had been placed on a prescription-only basis. At the same time, neither attapulgite nor polycarbophil were commercially available. Since then, however, several attapulgite- and polycarbophil-containing products have been marketed.

In April, 1986, FDA published its tentative final monograph on antidiarrheal drug product ingredients. This placed four ingredients in the "unsafe or ineffective" (Category II) group. Another 17 items were rated as having some, but insufficient proof of efficacy (Category III). Table 3 lists these.

Manufacturers of these latter items have until April 30, 1987, to prove their effectiveness. If they are unable to do so, the manufacturers will be required to reformulate their products to include attapulgite or polycarbophil, or remove them from the

marketplace.

While reviewing the antidiarrheals, FDA held that such drugs must be proven by objective measurements to be effective in treating, controlling, or stopping symptoms of diarrhea. Having proven this, their labeling should clearly reflect the intended results. These results, or indications, have been divided into three categories:

1. "For treatment of diarrhea, or to control/stop diarrhea."

2. "Reduces the number of bowel movements in diarrhea."

3. "Improve the consistency of loose, watery bowel movements in diarrhea." Additionally, manufacturers can state, if proven, "reduces/stops abdominal cramps or pain."

Adsorbent Antidiarrheals

Adsorbent agents represent the most commonly used antidiarrheals. They are nonspecific in activity in that they adsorb nutrients and enzymes, as well as toxins, bacteria, and other diarrhea-causing substances from the G.I. tract. Common adsorbents include activated attapulgite, polycarbophil, and kaolin/pectin.

Activated attapulgite, an anhydrous magnesium-aluminum silicate, was the first OTC antidiarrheal to meet the test of effectiveness. It was found to be superior to kaolin as an adsorbent for alkaloids, toxins, bacteria, and certain strains of enteroviruses. Activated attapulgite has already replaced kaolin/pectin in many commercial products.

TABLE 3

| Representative OTC Antidiarrheal Products | |
|---|--------------------------------------|
| Product | Ingredients |
| Bacid Capsules | Lactobacillus culture |
| Corrective Mixture | Bismuth subsalicylate |
| Diar-Aid Tablets | Attapulgite* |
| Dofus Capsules | Lactobacillus culture |
| Donnagel Suspension | Belladonna alkaloids, Kaolin, Pectin |
| Kaopectate Suspension | Kaolin, Pectin |
| Kaopectate Tablets | Attapulgite* |
| Lactinex Granules/Tablets | Lactobacillus culture |
| Mitrolan Tablets | Calcium polycarbophil* |
| Parepectolin Suspension | Kaolin, Paregoric, Pectin |
| Pecto Kay Suspension | Kaolin, Pectin |
| Pepto Bismol Suspension/Tablets | Bismuth subsalicylate |
| Polymagma Suspension | Attapulgite* |
| Quaigel Suspension | Attapulgite* |
| Rheaban Tablets | Attapulgite* |

*Ingredients meet FDA's 4/86 Tentative Final Monograph requirements for safety and efficacy.

An unusual adsorbent antidiarrheal is **polycarbophil**. This drug has also been ruled to be safe and effective for use as a bulk-forming laxative.

Polycarbophil adsorbs up to 60 times its own weight in water. Therefore, it can take up the excess fluids in patients with diarrhea, thus decreasing the liquidity and urgency of bowel movements, and conversely, increase the bulk of stools for patients with constipation.

Polycarbophil and calcium polycarbophil are considered to be therapeutically identical. Calcium polycarbophil does not adsorb water, so it can be formulated as a liquid. In the stomach, calcium ions are replaced by hydrogen ions, and it is converted to polycarbophil, which then exerts its hydroscopic effect in the intestine.

The Special Cases: Bismuth Subsalicylate, Opiates, and Kaolin/Pectin

Bismuth subsalicylate (an ingredient in Pepto Bismol) is enigmatic because it is also claimed to be effective in treating nausea, indigestion and upset stomach. The FDA-imposed rules (monographs) for those OTC products have not yet been finalized.

The FDA/OTC panel placed **opiates** in Category I, but FDA transferred them to the "needs more study" category. While paregoric is Schedule III and opiates are Schedule II under the Controlled Substances Act, and both require a prescription for sale, products "with not more than 100 mg opium per 100 ml, or 100 gm total may be exempt from prescription-only status and placed in Schedule V." This is appropriate, "...provided that such preparations contain one or more non-narcotic active ingredients in sufficient proportion to confer upon the preparation valuable medicinal qualities other than that possessed by the narcotic drug alone." Therefore, the possibility for a future shift to OTC status exists.

Even though kaolin/pectin/paregoric combinations have been marketed for years and remain available as of February 1987, FDA placed them in Category III. Evidence of effectiveness has never been submitted. FDA announced in its 4/86 no-

tice that manufacturers had one year from that date to comply. If unable to do so, they will no longer be allowed to market them.

Overview

Self-treatable diarrhea is usually self-limiting. The antidiarrheals approved by the OTC review (attapulgite and polycarbophil to date) should reduce the liquidity and frequency of bowel movements. Body fluid and electrolyte balance should also be maintained. When diarrhea becomes severe, or persists beyond 3 days, physician diagnosis of the underlying cause and treatment should be sought.

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Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within four weeks.

Axid is indicated for maintenance therapy for duodenal ulcer patients, at a reduced dosage of 150 mg h.s. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known.

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H₂-receptor antagonists.

Precautions: General— Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy.

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests— False-positive tests for urubrobinogen with Multistix® may occur during therapy with nizatidine.

Drug Interactions— No interactions have been observed between Axid and theophylline, chlorazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement

compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, perinatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White Rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates. Although no studies have been conducted in lactating women, nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups.

Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo.

Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to Axid® (nizatidine, Lilly)

determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L), and in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antidiuretic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H₂-receptor antagonist. On previous occasions, the patient had experienced thrombocytopenia while taking other drugs.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported.

Overdosage: There is little clinical experience with overdosage of Axid in humans. If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous LD₅₀ values in the rat and mouse were 301 mg/kg and 232 mg/kg respectively.

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ARTHRITIS MANAGEMENT: COMPREHENSIVE APPROACH COMBATS DISEASE ON MANY FRONTS

When Janet G. developed stiff, painful knees, she avoided using them, spending long periods in front of the television set with her legs propped up. But Philip R., who experienced the same symptoms, used the opposite approach—performing daily deep knee bends in an effort to overcome his stiffness.

Which of these people was doing the right thing?

Neither. Janet actually increased her pain and stiffness by not moving enough; Philip further damaged his joints by subjecting them to excessive strain.

Both behaved as they did for the same reason: fear of becoming crippled and deformed. Janet's response was to give up and refuse to do anything; Philip attempted to force himself onward. Both suffered from feelings of worthlessness and depression.

Psychological Reactions to Arthritis

The outcome of arthritis depends not only on the disease process, but also on the individual's psychological reaction to it. Emotional upsets seem to aggravate the condition. And people with rheumatoid arthritis often go through emotional cycles similar to those experienced by the terminally ill:

- **Denial.** The person thinks that arthritis is not very serious and ignores the doctor's warnings to be less active. Family and friends frequently reinforce this attitude.
- **Bitterness.** The person realizes that pain and fatigue are forcing a limit to activity and that friends and family may perceive him or her negatively.
- **Depression.** The person recognizes that the disease is serious and chronic and will cause him or her to depend on others for help, but fears that no one will understand.
- **Coping.** The person learns to deal realistically with arthritis.

Some people with osteoarthritis also suffer from depression, anger and frustration and must make changes in their lifestyles. They, too, gradually learn to cope by accepting their illness and finding success in a treatment program.

Management of Arthritis

Good medical management can mean the difference between ability and disability. The best results are achieved through a team approach. The family doctor may recommend consultations with a *rheumatologist* (joint specialist) or *orthopedist* (bone specialist). Other health professionals may also treat the patient. Since treatment continues for a long time, many therapeutic activities are performed by the patient at home, with periodic visits to a doctor or clinic.

"Although we can't cure arthritis, we can slow it down and help people learn to live with it," says Frederic McDuffie, M.D., professor of medicine at Emory University in Atlanta and medical director of the Arthritis Foundation. "Patient education may be the most important thing we do, and it's not toxic like some drugs."

Role of the Arthritis Foundation

Founded in 1948, the Arthritis Foundation supports research, training of arthritis specialists, public education about arthritis and help for patients. Local chapters distribute literature about the disease and provide information about specialists, clinics and other local agencies that offer physical and economic assistance. The Arthritis Foundation also helps make available Continuing Medical Education courses for internists, general practitioners and other physicians involved in treating arthritis.

Health Care Team

The *physician* makes the diagnosis, prescribes medication and recommends and supervises a treatment plan that usually includes exercise, rest, heat and perhaps surgery. The *physical therapist* helps reduce inflammation, maintain function and relieve pain through exercise and applications of heat and cold. This therapist instructs the person with arthritis in daily management of the disease.

The *occupational therapist* teaches the arthritic individual methods of joint protection, energy conservation and the use of splints or assistive devices that permit function without causing joint damage. Supporting these team members is the *nurse*, who helps in activities of daily living that the patient initially cannot do and assists in monitoring the effects of treatment. The *social worker* helps the individual make vocational and psychosocial adjustments and assists family members to develop effective coping methods.

Role of the Patient

"The informed patient is a vital member of the health care team," says Robert J. Smith, Ph.D., senior research scientist in arthritis with The Upjohn Company. It is the patient who is responsible for carrying out most aspects of arthritis management.

Exercise and Rest. Exercise keeps joints from "freezing" into one position and strengthens muscles around the joints, providing support and pain relief. Prescribed daily exercises put joints gently through their full range of motion. Since pain limits the performance of the exercises, this activity should be preceded by heat application or other pain-relieving maneuvers. Excessive or improper exercise can worsen joint symptoms, and during periods of acute inflammation, rest is more important than exercise. Although rest helps relieve strain on affected joints, too much rest can make movement difficult. So a proper rest-exercise balance must be planned.

Pain Relief. Temporary pain relief can be achieved by several methods. In addition to medication, the chief approach is based on application of *heat or cold*. Wet heat (such as baths, showers and hot packs) is more helpful than dry heat (heating pads, hot water bottles) or cold. Most people with arthritis feel more pain and stiffness when they get up in the morning, so the doctor may recommend a hot bath at that time. Whirlpool baths also provide massage, but the heat is what helps the joints. Ointments with oil of wintergreen warm the skin and can be briefly helpful.

Transcutaneous Electrical Nerve Stimulation (TENS). A device for TENS, which sometimes can be used in the patient's home, helps relieve pain by stimulating nerves near the skin surface.

Assistive Devices and Lifestyle Changes. Removable *splints* reduce joint inflammation and keep joints in a normal position to help prevent deformity. They are most often used for the wrists, fingers, knees, ankles and feet. Splints also can be used to protect arthritic joints during activity. The strain of weight-bearing can be reduced by the use of *canes or crutches*.

Various inexpensive devices can assist in carrying out daily activities like bathing, dressing and eating. Among them are bath seats, raised toilet seats, angled toothbrushes and combs for easier holding and stair rails. If therapy plus assistive devices are not sufficient, modification of activities should be arranged. Many

tasks can be performed while sitting, items can be rearranged to be within easy reach, and new interests found to replace what no longer can be done. Obesity is a danger because it places added strain on weight-bearing joints.

Quackery

Quackery—making claims that misrepresent a purported remedy—is a bigger business in arthritis than in any other illness. Patients must beware of falling prey to quackery in their efforts to obtain relief. Among the worthless treatments are bee venoms, food supplements, herbs, sea products, copper bracelets, vibrators and radioactive devices. The "testimonials" often offered to support these are not reliable evidence, because:

- patients may have been taking other medicines that helped them;
- up to half the people get better no matter what they take because they believe they will (the placebo effect); and
- arthritis often has remissions that may occur coincidentally just when a person tries a new remedy.

Some tip-offs for identifying quack remedies include:

- claims of a "cure" for arthritis (none yet exists);
- offers of "secret" or "exclusive" remedies;
- treatments described as "cleansing the body of toxins"; or
- condemnations of drugs and surgery.

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Dimethyl sulfoxide (DMSO) is a widely publicized drug with unknown long-term effects. Research is under way to establish what role, if any, it might have in arthritis therapy. At this time, it is not approved for arthritis, and it may be dangerous.

Adjunctive Treatments

If maximum benefits are not obtained from physical and drug therapy along with rest and joint protection, other approaches are available.

Acupuncture. This ancient Chinese treatment is claimed to relieve pain and is performed by inserting needles under the skin at specific sites. However, recent studies suggest that acupuncture may be no better than placebo for this purpose.

Surgery. Operations have been developed to relieve pain, restore function and correct deformity resulting from arthritic joint damage. Pain relief is the most reliable result of joint surgery and the major reason for it. Movement and function are not always regained, and the operation is only the first step in restoring a joint. The patient must subsequently follow a program of medication, joint protection, rest and exercise in order to receive maximum benefit. Several different types of surgery are performed, including removal of the diseased joint lining, removal of bone, bone fusion and joint reconstruction or replacement. The most reliable—hip replacement—has a success rate exceeding 90 percent.

QUIZ

TEST YOUR KNOWLEDGE OF ARTHRITIS

1. Is arthritis a single disease?
2. What are the most common forms of arthritis?
3. What are the major warning signs of arthritis?
4. Is early diagnosis important?
5. Do only the elderly get arthritis?
6. Why seek medical treatment for arthritis when there is no cure?
7. Does rheumatoid arthritis affect only the joints?
8. Can diet lessen or prevent arthritis?
9. Can rheumatoid arthritis go away by itself?
10. Is medication the only important factor in a treatment program?
11. Will a warm, dry climate help arthritis?
12. If aspirin relieves arthritis pain, is medical treatment necessary?

Answers on Page 26.

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The Vast Unknown: Unanswered Questions Challenge Arthritis Research

Trying to solve the riddle of arthritis is like trying to track down agents in a conspiracy of destruction. Many components of the immune system have been implicated or are under suspicion as promoters of rheumatoid arthritis (RA), but investigators haven't located the organizer of the scheme (possibly a virus), nor do they agree on which member of the immune system is the chief co-conspirator.

Breaking up the conspiracy also is a difficult proposition.

"We have to attack the disease by preventing certain immune-system cells from communicating with each other," says Robert J. Smith, Ph.D., a senior research scientist with The Upjohn Company.

The picture in osteoarthritis (OA) is even less clear. Joint damage was originally ascribed to normal wear and tear, but many investigators now believe that disease processes are involved here, too.

1. What starts the rheumatoid arthritis process?

RA is considered an autoimmune (body against itself) condition. It is not known why immune system cells congregate in the rheumatoid joint.

"There are certain people who may be genetically vulnerable to agents thought to trigger RA, such as viruses and bacteria," says Thomas G. Kantor, M.D., professor of clinical medicine at New York University School of Medicine in New York City. "But it's not purely a genetic disease. We usually can't trace a history in families." The triggering agent starts an abnormal immune system response that results in *inflammation* (localized swelling, redness, heat and white blood cell invasion) and ultimately destruction.

2. Which parts of the immune system play key roles in rheumatoid arthritis?

A brief review of the function of some immune system components—white blood cells and their secretions—will help in understanding the disease process. *Neutrophils* are small cells that engulf and destroy in-

vaders and produce chemicals that enhance inflammation. *Macrophages* are larger scavengers that appear next and also "eat" invaders and damaged cells. They produce various chemicals that stimulate other immune system factors.

There are two main kinds of *lymphocytes*: B cells and T cells. *B cells* can develop into specialized cells that produce antibodies. These compounds attach to an inactivate invaders, forming immune complexes which are then engulfed and "eaten." In RA, particular antibodies called *rheumatoid factors* are produced. These latch onto other antibodies and seem to stimulate inflammation.

Helper T cells produce substances that increase the number and activity of defensive cells. In contrast, *suppressor T cells* secrete substances that protect the body from its own immune system and inhibit the action of other B and T cells. RA victims may have suppressor T cell deficiencies.

A group of hormone-like substances called *prostaglandins* are being studied to determine what role they play in RA. They were primarily considered mediators of inflammation, but their functions now appear to be more complex.

"Prostaglandins stimulate neutrophil activity and production of rheumatoid factor and destructive enzymes, among other things," says James S. Goodwin, M.D., chief of gerontology at the University of New Mexico School of Medicine in Albuquerque. According to Dr. Goodwin's hypothesis, prostaglandins inhibit suppressor T cells that would otherwise slow or halt the abnormal immune responses.

Without the suppressor action, rheumatoid factor continues to form immune complexes in arthritic joints. Attempting to digest these complexes, neutrophils and macrophages release cartilage-damaging enzymes as well as additional prostaglandins that continue the cycle of inflammation.

Many prostaglandins are derived from arachidonic acid. The body has at least two pathways for transforming arachidonic acid. One pathway produces prostaglandins; the other, *leukotrienes*.

Neutrophils secrete a particular leukotriene called LTB₄, which is found in the joints of RA patients. It attracts white blood cells that release tissue-damaging chemicals. More cells follow in another clean-up attempt, and the process accelerates.

"Prostaglandins seem associated with acute inflammation and LTB₄ with chronic inflammation," says Dr. Kantor. "LTB₄ is a powerful attractant to white blood cells, including macrophages, which stay at the site a long time."

Gerald Weissmann, M.D., professor of medicine and director of the division of rheumatology at New York University School of Medicine, believes that neutrophils and LTB₄ are major culprits in the inflammatory process.

But the evidence is far from complete. Another viewpoint is that once the process begins, the main villains in RA are the macrophages, which produce various destructive agents including prostaglandins, enzymes, oxygen radicals and *interleukin-1* (IL-1).

"In excess, IL-1 stimulates T and B cells, fibroblasts, hepatocytes, chondrocytes and other synovial cells to enhance the production of antibodies, prostaglandins, tissue-destructive enzymes and acute-phase proteins, thereby exacerbating joint damage," says Daniel E. Tracey, Ph.D., an Upjohn research scientist studying arthritis.

Recent reports indicate that RA patients may have an impaired suppressor T cell response to infection by the Epstein-Barr virus, one of the viruses suspected of triggering the disease. It also has been reported, although this finding is considered controversial, that they seem to make inadequate amounts of *interferon*, a substance that assists the suppressor T cells to function. Because of the suppressor T cells impairment, virus-infected B cells proliferate and may lead to a continuous, destructive immune response in the joint.

3. What do nonsteroidal anti-inflammatory drugs (NSAIDs) do in RA and OA?

NSAIDs reduce the production of prostaglandins by inhibiting one or more steps in the pathway that produces them. It is generally believed that NSAIDs offer only temporary relief of RA, but some evidence now suggests that these medications may suppress the disease process itself. One study showed that NSAIDs enhance suppressor T cell function and inhibit the production of rheumatoid factor, perhaps by reducing prostaglandin production. However, the anti-inflammatory effects of NSAIDs can't be completely explained by this mechanism alone. Their benefits may be due in part to their suppression of inflammatory cell migration and activation. And investigators are studying the possibility that some NSAIDs may inhibit the leukotriene-producing pathway as well.

NSAIDs also may quell factors in the osteoarthritis process. Patients in one study reported better results with a pain-relieving anti-inflammatory drug than with a medication that offered pain relief alone. Other studies suggest that NSAIDs may actually halt progressive joint deterioration or may prevent OA from developing in an injured joint.

4. What new treatments exist for rheumatoid arthritis?

Flurbiprofen (Ansaid Tablets, Upjohn), which is not yet available in the U.S., is a new NSAID that appears to have excellent pain-relieving ability. In a study of over 700 people with RA, it produced significant improvement in grip strength, morning stiffness, functional capacity and pain severity.

Captopril (Capoten, Squibb), a drug currently used to treat hypertension, has structural features in common with the anti-arthritis drug penicillamine. It showed promise in a study of 15 subjects, but needs to be evaluated on a larger scale.

A factor derived from *cobra venom* blocked swelling and destruction of joint cartilage in animal tests and may lead to development of yet other drugs for RA.

Plasmapheresis, a process that screens lymphocytes out of the blood, is expensive and produces only short-lived benefits. A rebound phenomenon may occur that leaves the patient worse off than before, according to James F. Fries, M.D., associate professor of medicine at Stanford University School of Medicine in Palo Alto, Calif. He views the treatment as neither practical or recommended.

Total lymphoid irradiation is an experimental treatment that has been used on only 70 people. Joint inflammation and lymphocyte count were greatly reduced, and the count may remain low for years. This treatment is not a cure, however, because not all symptoms respond. Side effects were common, and long-term dangers are not known.

5. Is osteoarthritis a normal process of aging or a disease?

"Osteoarthritis is an umbrella term for several separate conditions," says David S. Howell, M.D., professor of medicine and director of the arthritis division at the University of Miami School of Medicine. "Some forms are definitely a disease, and one is predominantly an aging process with the history of a person's physical activity scored on the cartilage. This form involves degeneration without adequate repair—the results of prolonged use of material that wears out. Some people feel that parts of the aging process itself can be considered a disease, and others believe that aging is a normal process. It's a matter of definition."

Many investigators consider OA a disease.

"Not all old people have symptomatic degenerative joint disease, and some people in their 40s are affected. So it's clearly not normal," says Daniel J. McCarty, M.D., professor and chairman of medicine at the Medical College of Wisconsin in Milwaukee. One possibility: OA is caused by a disturbance of the mechanism for repair of trivial daily mechanical injury. Aging may not directly result in OA, but it may produce joint changes necessary for the OA process to begin or progress.

6. Is inflammation a frequent and important factor in osteoarthritis?

Some evidence suggests that early changes in the cartilage are not inflammatory, but inflammation is a common late result, possibly caused by fragments of cartilage and bone or crystal deposits.

"Frequently there is some inflammation present," says Dr. Howell. "It's a hotly debated point whether the inflammation may sometimes come first and its by-products damage the joint or whether joint damage prevalently leads to inflammation. Probably the former is true only under rare circumstances."

7. Is osteoarthritis reversible?

Although cartilage has limited repair capability, other cells can facilitate repair under the right conditions. The new material produced, while not identical to the original cartilage, often permits normal joint function and prevents further deterioration. Much of the controversy about joint healing stems from a failure to consider joint function rather than cartilage appearance as the most important aspect of healing.

The upshot is that many questions about arthritis are still unanswered. In this light, it is truly remarkable that medical science has been as effective as it has in treating arthritic diseases.



PHARMACIST TELLS SENATE DRUG LABELING IS "INADEQUATE"

Too often adverse drug reactions among the elderly "go unnoticed." That is what William D. Simonson, gerontologist and Assistant Professor of Pharmacy in the College of Pharmacy at Oregon State University, Corvallis, told the Senate Special Committee on Aging on March 25, 1988. He called for more complete geriatric drug labeling, testifying that FDA labeling requirements are "inadequate."

"In my opinion the biggest problem caused by adverse drug reactions in the elderly is not the adverse reaction itself, although the outcomes can be tragic, but rather the fact that these adverse reactions often go unnoticed," he testified. Simonson cited a "mistaken attitude" by many health professionals about the elderly. He said that often they are stereotyped as being confused, depressed, anorexic, weak and lethargic and exhibiting ataxia, forgetfulness, tremor, constipation, diarrhea and urinary retention. This he feels is unfair because most elderly persons experience none of these characteristics.

As a result of this stereotyping, Simonson said, some professionals overlook medications as the potential cause for their patients' deterioration. The problem could be adverse drug reactions.

"I often wonder how many elderly patients have been sentenced to a life of institutionalized chemical restraint simply because they experienced adverse drug reactions manifested as confusion, or psychosis," he told the committee.

Simonson called for labeling that includes a specific statement of the likelihood of adverse drug reactions occurring in elderly patients. In addition, he said, specific geriatric dosage requirements should be prominently noted when available. If they are not, there should be a general statement on potential alterations in dosage requirements.

He also said the FDA should require adequate geriatric studies be performed prior to approval of any new drug. This will reveal valuable pharmacokinetic and pharmacodynamic information about the drug, which would help determine if a specific geriatric dosage would be necessary. He also suggested post marketing surveillance so that adverse reactions could be noticed earlier.

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Community Forum

This is the second in a regular series of letters and comments received by the Employee/Employer Relations Committee and published here in hopes of opening up a dialogue on issues of concern to employee pharmacists and their employers.

This month's letter brings up an issue that has been discussed during many committee meetings. The problem of overwork and its relationship to the present man-power shortage, job stress, and proper patient care has been reviewed. In the past, the consensus of the committee has always been that a pharmacist is the best judge of their own ability to fill prescriptions.

The Board of Pharmacy has appeared to take the stand that numerical limits on prescription filling, even if they were regulatable, are too restrictive (pharmacists have such varied abilities), are non-enforceable, and cannot be set. Yet the board does place a limit on the number of technician that one pharmacist can supervise.

Unfortunately many pharmacies do place nu-

meric limits on their pharmacists. Such limits are usually cited in approval or denial of requests for additional personnel to assist the pharmacist.

The lack of substantiated complaints is another reason why the Board has not been able to address this issue thoroughly. The Committee itself, after discussing these problems, finds that most employees will not make formal complaints, citing backlash from employers as the main deterrent.

Certainly the issue demands a response, but most pharmacy employees, employers, leaders, and regulators appear to be waiting for someone else to take the first step. Hopefully this committee can take that first step before patient care is compromised to such a point that serious consequences result and dictate a reactionary legal and regulatory response. But because of the formidable complexities involved, every solution proposed so far has elicited immediate, skeptical, and some times vehement reactions. A broader exchange is needed and a better consensus needs to be formed.

Employee/Employer Committee
Maryland Pharmacist Association
650 Lombard Street
Baltimore, Maryland

A recent experience concerning employee/employer relations prompted me to write. I have been working for a large local chain for the last 4 years. With third party plans and still being a manual system, the workload became increasingly worse and the pressure more difficult to deal with. The situation peaked when the pharmacist on the opposite shift left for maternity leave and was replaced by a recent graduate who had not yet developed the speed or confidence to handle a busy store. I began to compensate by putting in additional hours (5 to 10 hours per week for 3 months—without pay) hoping to alleviate what I thought was a temporary situation. However, faced with long backups, inability to complete necessary paperwork, and possible prescription errors, I contacted the district manager (who is also a pharmacist). The response from the district manager was defensive and accusatory. He did not offer any support, in fact, he made me feel like a "wimp" and he attacked me personally. I felt he no longer was aware of the responsibilities and pressures of pharmacy practice. I felt he believed speed and the ability to produce THE PRESCRIPTION was the only *job* of the pharmacist. Needless to say, I was devastated by this attitude. Patients and "non-pharmacist" are ignorant of the training and demands of practice, however, for a

pharmacist district manager to be ignorant of these factors is inexcusable.

My purpose in writing you is several fold. First, I wonder if other pharmacists have been subjected to this type of humiliation or professional disrespect from their superiors, be they company officials or owners of independent stores. Secondly, does your committee have any suggestions for the employee pharmacist to help cope with this type of attitude. Finally, I think it would be beneficial for your committee to sponsor workshops or CE programs on personnel relations so that persons in supervisory positions would be better equipped to deal with situations.

However, in reality, the problem seems to be one of manners and showing an employee the respect and courtesy he/she deserves as *human beings* not just as pharmacists. As I said in reference to this situation as I asked for a transfer, "He is the boss and has a right to behave any way he chooses. However, I have a right not to be subjected to rude and unfounded comments as well as the lack of respect and support." As a result, he lost one of the best employees he ever had, or will have. I think it would be interesting for any other pharmacists that have had similar situations arise to contact your committee. Perhaps you could institute a column in the journal dealing with employer/employee relations.

Thank you for your time.

Name withheld

TAILOR ARTHRITIS MEDICATION TO THE INDIVIDUAL AND THE DISEASE

Individual variation seems the rule rather than the exception in arthritis. Not only are there more than 100 different forms of arthritis, but a given form can run many alternate courses. Moreover, people with the same disease vary in their responses to any one medication.

For these reasons, physicians who treat arthritis emphasize the need to tailor medications to the individual and to closely monitor that person's response.

Medications widely used for arthritis, particularly rheumatoid arthritis (RA) and osteoarthritis (OA)—two very different diseases—are discussed below.

Nonsteroidal Anti-Inflammatory Drugs Fight Pain, Inflammation

Commonly used to treat most forms of arthritis are the first-line medications called *nonsteroidal anti-inflammatory drugs (NSAIDs)*. This family of compounds—which includes aspirin and a host of newer agents such as ibuprofen (Motrin Tablets, Upjohn)—relieves pain and, when in high enough dosages, reduces inflammation while improving joint function. These actions probably are due to NSAID inhibition of hormone-like substances called *prostaglandins*.

Some prostaglandins produced by body cells increase the sensitivity of nerve cells to pain and, therefore, amplify the pain signals transmitted from the injured area to the brain. Certain prostaglandins also play a role in *inflammation*—the localized swelling, redness, heat and white blood cell invasion that is integral to rheumatoid arthritis and many other forms of the disease. Inflammation may accompany joint degeneration in osteoarthritis as well.

"In England, (non-aspirin) NSAIDs are used almost exclusively in preference to aspirin," says Frederic McDuffie, M.D., professor of medicine at Emory University in Atlanta and medical director of the Arthritis Foundation. "The main disadvantage of aspirin is that it can cause stomach upset and ulcers."

"I usually start patients on a (non-aspirin) NSAID, and sometimes on aspirin," says Wilbur J. Blechman, M.D., clinical professor of medicine at the University of Miami School of Medicine. "But I've run into more side effects with aspirin."

It sometimes takes a few trials to find the drug that best suits a particular person. Motrin is considered one of the NSAIDs easiest on the digestive system and, therefore, well tolerated by many patients.

The Dangers of Self-Medication

Because aspirin often is an effective arthritis pain-reliever, many people who suffer joint pain take aspirin rather than consult a physician. There are, however, compelling reasons why this course is unwise:

1. Proper diagnosis of the arthritis type is essential for appropriate treatment selection.
2. Moderate doses of aspirin may be adequate to mask pain, the major warning signal. However, a regular regimen of *larger doses* is required to *reduce inflammation*—a crucial factor in prevention of joint destruction.
3. Appropriate aspirin dosage varies with the individual and should be matched by a physician to the patient's weight, metabolism and severity of disease.
4. Prolonged aspirin consumption can lead to digestive system complications ranging from stomach upset to internal bleeding and sometimes aspirin toxicity. While physicians frequently start patients on aspirin because of its low cost, many people can't tolerate it and must be switched to one of the newer prescription NSAIDs. (Note: Acetaminophen, the active ingredient in Tylenol and Datril, is *not* an effective anti-inflammatory agent.)

Continued on Page 20

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Although a low-dose, nonprescription form of ibuprofen (Nuprin) is now available to treat headaches, menstrual cramps and minor aches and pains, sustained higher doses usually are needed to counter arthritis inflammation. High-dose, long-duration treatment with any drug should be undertaken only at a doctor's recommendation and with regular medical supervision.

Steroid Hormones: When Should They Be Used?

The discovery 35 years ago of the relief afforded rheumatoid arthritis sufferers by *corticosteroids*—hydrocortisone and its chemical relatives—was considered significant enough to merit a Nobel Prize.

But researchers since have found that steroid hormones are not a cure for arthritis: Symptoms often become worse unless such drugs are tapered off slowly before withdrawal. And nearly all patients given long-term, high-dose steroids encounter potentially serious side effects. These drawbacks restrict the drugs' usefulness in arthritis to certain well-defined circumstances.

Osteoarthritis that affects only one or two joints may be treated by steroid injection into those joints. Experts recommend spacing injections a few months apart and warn that numerous repetitions can lead to joint damage.

In rheumatoid arthritis, corticosteroids taken by mouth or injected into the bloodstream are reserved for cases of rapidly progressing disease unresponsive to other treatments. When first-line drugs—NSAIDs—are insufficient alone, steroids sometimes bring relief until second-line drugs called *remititive agents* begin to work. Steroids also are administered to counter potentially life-threatening complications such as inflamed, weakened arteries.

Steroid use is more common for systemic lupus erythematosus and its complications. And short-term therapy sometimes is recommended for people with other forms of arthritis.

When prescribing steroids for arthritis, experts generally prefer short-acting drugs, such as methylprednisolone (Medrol Tablets or Solu-medrol Sterile Solution, Upjohn). These interfere less with the body's daily cycle of hormone secretion and, therefore, cause fewer side effects.

Efforts to reduce steroid side effects have focused recently on *high-dose pulse therapy*—10 to 100 times the usual doses of methylprednisolone repeated, in some instances, on a few consecutive or alternate days. Initial trials suggest that this technique may produce more rapid control in a crisis. Whether it significantly reduces steroid side effects remains to be seen.

Toxicity a Problem With Second-Line Drugs for Rheumatoid Arthritis

Variously called *remititive agents*, *anti-rheumatic*, *disease-modifying* or *slow-acting drugs*, these compounds are employed when rheumatoid arthritis can't

be controlled adequately by NSAIDs alone. These drugs promise medium-term benefits to large numbers of patients, but at substantial risk of toxicity.

The drugs do seem to retard joint destruction and, hence, slow the progress of the disease. They also relieve pain, enhance joint function and reduce levels of joint-damaging proteins. But these benefits often aren't apparent until months after treatment begins. Whether they lead in some cases to joint repair is an open question.

Among the remittive agents commonly used or presently being tested (usually in combination with NSAIDs) are:

1. *Gold Salts.* Gold injections have been used for about 50 years to treat RA. An oral gold drug called auranofin (Ridaura, Smith Kline & French) may soon be available. It allows low daily doses that seem to be less toxic. Researchers hope that oral gold will prove safe enough to be an ancillary first-line agent for patients with progressive disease. About 70 percent of patients with early RA now benefit from gold injections, but fully one-third of those treated develop signs of drug toxicity, which may necessitate ending the treatment.
2. *D-Penicillamine* (Cuprimine, Merck Sharp & Dohme; Depen, Wallace). This chemical relative of penicillin can produce dramatic improvement when given orally, but seems even more toxic than gold salts. Side effects force cessation of treatment in about half the cases. The problem is reduced if patients are started on low doses that are raised slowly. In one study, X-rays made after two years of penicillamine treatment showed it apparently more effective than gold injections in slowing joint degeneration.
3. *Anti-Malarial Agents.* Although the principal oral drug of this class, hydroxychloroquine (Plaquenil, Winthrop), is considered less effective than those above, it often is better tolerated. Plaquenil partially suppresses symptoms in 70 percent of patients. The most common side effect, visual impairment, is rare at the low doses now recommended. And it sometimes is useful for systemic lupus erythematosus as well.

Third-Line Drugs

In about 5 percent of people, severe rheumatoid arthritis fails to respond to any of these measures. *Rheumatologists*—experts in joint disease—may then resort to *cytotoxic* (anti-cancer) *agents* or other *immune system suppressants* (now used primarily to prevent rejection of transplants). Although these often reduce inflammation and immune system hyperactivity—particularly when combined with NSAIDs and second-line agents—all but one are considered experimental when used for RA. Because each has its own particular

hazards, they generally are reserved for intractable, crippling or life-threatening cases. Four drugs seem especially effective: axathioprine and chlorambucil (Imuran and Leukeran, Burroughs Wellcome), cyclophosphamide (Cytoxan, Mead Johnson) and methotrexate (Mexate, Bristol).

The Search Goes On

Despite considerable strides in the treatment of rheumatoid arthritis, the drugs now available seem to offer largely symptomatic relief and possibly a slowing of the disease—but often at considerable risk. Researchers continue their quest for drugs that will correct the underlying defect(s) in RA and other autoimmune diseases. Many types of immune system cells and secretions wreak their special brands of havoc in rheumatoid joints. Scientists must first determine which initiates the self-destructive processes before they can find an agent to selectively counter it.

Conference on The Role of Pharmacy Technicians Planned

The University of Maryland Center on Drugs and Public Policy is planning an invitational conference on the role and impact of pharmacy technicians on the practice of pharmacy. The conference, to be held in Baltimore, October 29th–November 1st, will include representatives from all sectors of pharmacy. The goal of the meeting is to assess critically the current and projected place of technical personnel in pharmacy, and to examine the implications for pharmacy of attempting to better define such personnel in terms of function, training, recognition, and legal status.

A steering committee for the conference will be chaired by the Center's Director David Knapp, Ph.D.

The Center on Drugs and Public Policy is a research unit of the University of Maryland Graduate School that explores policy issues related to the development, provision and payment for prescription drugs. The Center is a joint venture by the School of Pharmacy and the Policy Sciences Graduate Program. The Center's expertise includes pharmacists as well as economists and political scientists.

Tween Scripts

By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.



For years, pharmacists have seemed to suffer from the Rodney Dangerfield Syndrome. In our own eyes, at least, it seems that "we get no respect."

National pollsters know differently, however, because consumer surveys conducted by the Gallup Organization in 1981, 1983 and 1985 consistently placed pharmacists just after the clergy and ahead of other groups in rankings of the nation's most trusted professions. The proportion of respondents who gave pharmacy a top ranking has grown steadily through the years.

The 1987 SRI Gallup Poll reported that seventy percent of the 734 persons surveyed rated pharmacists' honesty and ethical standards in the "very high or high" categories, with the result that pharmacists have now achieved the standing of the most highly respected of all professions in the eyes of the American public, bypassing even the clergy.

The nationwide telephone survey showed that after pharmacists, in descending order, came dentists, physicians, clergy, college professors, bankers and lawyers.

This is a well-deserved honor for the pharmacy profession and particularly for those pharmacists on the front lines of health care delivery where daily patient encounters have resulted in the respect in which the profession is held.

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100 VARIETIES OF ARTHRITIS AFFLICT TOTAL OF 36 MILLION AMERICANS

The world has long admired the painting of Pierre Renoir. But few people realize that in his later years, Renoir's fingers were so crippled by arthritis that his paintbrush had to be strapped to his hand whenever he wished to paint.

Today's treatments often can prevent such disability. Yet much needless crippling still occurs because people frequently are unaware that arthritis is potentially serious or that effective therapy is available.

"Early diagnosis is crucial so the appropriate treatment can begin before joints become irreversibly damaged," says Colin J. Dunn, Ph.D., an arthritis research with The Upjohn Company.

Arthritis means "joint inflammation." It is not a single disease, but rather a symptom that can occur in more than 100 acute and chronic conditions. *Rheumatism*, another frequently used term, is a vague label for a variety of joint and muscle aches and pains.

Arthritis has a staggering human and financial impact in the United States. According to the Arthritis Foundation, 36 million Americans are victims. Osteoarthritis afflicts 17 million of these, and another 7 million have rheumatoid arthritis. In addition, there are 2.5 million people with ankylosing spondylitis, 1.6 million with gout, more than 300,000 with lupus erythematosus and 300,000 with scleroderma, as well as 250,000 children with juvenile rheumatoid arthritis and an unknown number of people with infectious arthritis and soft tissue inflammations, such as bursitis and tendinitis.

Annual economic losses include an estimated \$4.7 billion in medical care, \$4.8 billion in lost wages, \$1 billion in lost income taxes, \$1 billion in disability aid and insurance, \$1.3 billion in lost homemaker services and \$1 billion wasted on quack treatments. The overall financial impact of arthritis totals approximately \$14 billion.

Osteoarthritis (OA)

Often described as a "wear and tear" disease, osteoarthritis seems related to strain on the joints. Although nearly everyone eventually develops some vestiges of OA, researchers now question the assumption that it is an inevitable part of aging. Victims are usually older people, and women have twice the OA incidence of men. Fingers and weight-bearing joints (knees, hips, spine) are most afflicted.

The bone ends that meet at a joint normally are covered with a shiny substance called *cartilage* that permits smooth movement between the bones. In OA, use, injury or infection causes the cartilage to wear away. Bone ends thicken and bony spurs may develop. The disease generally is mild, and rarely crippling, producing moderate pain. Unlike rheumatoid arthritis, it doesn't spread to multiple joints or involve the whole body. Many victims have OA only in the knees or hips, for example.

Symptoms, Diagnosis and Prognosis. Pain in and around joints is the main symptom, with the second most common symptom being loss of joint mobility. OA doesn't cause fever, weight loss or feelings of illness. Diagnosis is aided by X-rays and laboratory tests. While OA is presently incurable, treatment can relieve symptoms, improve joint function and may prevent further progress of the disease.

"Researchers are now working on medical and surgical means to improve the quality and quantity of cartilage repair," says David S. Howell, M.D., professor of medicine and director of the arthritis division at the University of Miami School of Medicine.

Rheumatoid Arthritis (RA)

The most crippling form of arthritis, rheumatoid arthritis, was the disease that compromised Renoir's ar-

tistry. RA usually starts between ages 20 and 45 and strikes three times as many women as men. It involves multiple joints, especially those of the hands and feet. The disease also can attack lungs, skin, blood vessels, muscles, spleen and heart. It is frequently characterized by remissions—months or years in which the pain, stiffness and swelling lessen or disappear.

Cause. Some people appear to be genetically predisposed to RA. The disease seems triggered by unidentified viruses or other factors that set off immune system malfunctions in these individuals. Normally, when invaders (called “antigens”) enter the body, certain white blood cells (particular *lymphocytes*) manufacture *antibodies*, proteins that inactivate the invaders by forming *immune complexes*. Scavenger cells then digest the complexes. (See illustration).

However, in RA, the lymphocytes release antibodies and other substances that damage the joint lining and cartilage instead of attacking invaders. In addition, digestive chemicals released by the scavengers escape into the joint fluid and cause further damage. Synovial (joint lining) and other cells pile up in the area under attack, forming *pannus*.

Symptoms. People with these major RA symptoms should see a doctor:

- painful, swollen joints for more than 6 weeks
- morning stiffness for an hour or more
- systemic symptoms such as fatigue or weight loss
- symmetrical joint involvement
- lumps under the skin near the elbow
- joint deformity

Diagnosis and Prognosis. An abnormal antibody known as *rheumatoid factor* is usually present in the blood of persons with rheumatoid arthritis, and blood tests indicate the presence of inflammation. Moreover, fluid extracted from involved joints contains many white blood cells. In 10 percent of cases, rheumatoid arthritis disappears by itself; in the remainder, proper treatment helps prevent deformity and crippling.

Systemic Lupus Erythematosus (SLE)

SLE is a collagen (connective tissue protein) disease. It affects 10 females for every male, and the incidence peaks between ages 15 and 25. Blacks run a higher risk of SLE than other groups. In 90 percent of cases, the disease involves the joints. But it also can damage the muscles, skin, kidneys, nervous system, lungs, heart, blood-forming organs and immune system. As with rheumatoid arthritis, people with lupus produce antibodies against their own tissues, and the resulting immune complexes cause injurious deposits around the body. A virus is believed to be one of the triggers in genetically predisposed individuals. Symptoms of SLE wax and wane in periodic flare-ups and remissions.

Symptoms. First signs may be fever, weakness, fatigue or weight loss. A rash may appear on the arms, neck or face, sometimes forming a butterfly-shaped pattern over the nose and cheeks. Exposure to sun may make the rash appear or worsen. Joint pain may manifest itself in the hands, wrists, elbows, knees or ankles. Later, varied symptoms associated with organ damage may be seen.

Diagnosis and Prognosis. Diagnosis often is difficult. Blood tests—including one for a characteristic antibody—generally are performed. The course of the disease usually can be predicted from the pattern of organ involvement during the first two years. The five-year survival rate now exceeds 90 percent; 30 years ago, it was only 50 percent.

Other Major Forms of Arthritis

Juvenile Rheumatoid Arthritis. This form strikes children, often before the age of seven. In most cases, it first affects their knees. The disease also may begin with a high fever and rash that lasts for weeks or months and is not accompanied by joint involvement. Eye inflammation and growth abnormalities may occur. Treatment generally prevents permanent damage. About 70 percent of the children out-grow the disease, 20 percent have residual effects, and 10 percent remain arthritic.

Scleroderma. Literally “hardening of the skin,” scleroderma is another connective tissue disease that can produce arthritis. In addition to skin symptoms, internal organs often become inflamed. More women than men are affected; most are in their 40s and 50s. The disease can progress rapidly or become chronic. Treatment is not completely successful.

Ankylosing Spondylitis. This is an inflammatory disease of the spine to which there seems to be a strong hereditary predisposition. A genetic marker called B-27 is found on cells of 95 percent of patients. The disease begins in the late teens and early 20s. It was once believed to be much more common in men, but recent evidence suggests otherwise. Loss of spinal mobility occurs progressively. A bent-over position eases back pain, so permanent curvature may develop in the untreated patient. Medication, postural training and daily exercise prevent significant disability in most patients.

Infectious Arthritis. Gonorrhea—a sexually-transmitted bacterial disease—is a common cause of infectious arthritis, but other infections can produce similar joint symptoms. While gonococcal arthritis often involves many joints and moves quickly around the body, other infections usually attack only a single joint. Early treatment is vital to prevent rapid joint destruction.

Soft Tissue Inflammation. *Bursitis* and *tendinitis* are common forms of soft tissue inflammation. A bursa is a small fluid-filled sac that serves as a cushion at a poten-

tial friction point between bones and muscles. Irritation from pressure or injury can inflame it, producing pain and swelling. The shoulder is most commonly affected. Tendons connect muscles to bones, and tendinitis occurs most frequently where tendons pass over bony prominences or through narrow canals. "Tennis elbow" is an example. Treatments include pain-relieving drugs, cortisone injections, rest, physical therapy and sometimes surgery.

Gout. Gout is one of the few forms of arthritis that can be completely controlled. It usually begins between ages 40 and 50, and 80 to 90 percent of its victims are men. The disease often results from an inherited defect in body chemistry, but it may also be caused by diuretic pills. Uric acid, a waste product resulting from the breakdown of food substances called purines, is over-produced or not excreted fast enough by the kidneys. In 10 percent of those with excess uric acid in their blood, needle-like crystals form in joints, leading to severe inflammation with heat, swelling and great tenderness. In 75 percent of gout cases, the big toe is attacked first.

If the disease is not treated, the affected joints become damaged. Diagnosis is made by removing fluid from an affected joint to identify the presence of urate crystals. A life-long regimen of diet and/or medication can prevent attacks or lessen their severity.

Answers to Arthritis Quiz

1. No. The term arthritis refers to approximately 100 different conditions that involve pain in joints and connective tissues.
2. The five main types are:
 - A. *rheumatoid arthritis*, which can cripple;
 - B. *osteoarthritis*, which is usually mild and is most common in older people;
 - C. *ankylosing spondylitis*, which affects the spine;
 - D. *systemic lupus erythematosus*, which damages organs throughout the body and primarily affects young women; and
 - E. *gout*, which is usually inherited, occurs mostly in men and is especially likely to involve joints of the foot, ankle or knee.
3. Chief symptoms include morning stiffness and recurrent or persistent joint pain.
4. Yes. Different forms of arthritis require different treatments, and treatment is most effective when started early.
5. No. Many athletes get osteoarthritis in injured joints, and rheumatoid arthritis can strike children and young adults.

6. The major forms are chronic, lifelong diseases, but continuing treatment is essential to minimize pain and potentially crippling joint damage.
7. No. Connective tissues throughout the body can be involved as well.
8. Good nutrition is important, but there is no evidence that particular elements in the diet have any effect on the major forms of arthritis except for gout. (Obesity, however, puts undue strain on weight-bearing joints and should be avoided.)
9. This usually happens on a temporary basis only and is called remission. Juvenile arthritis often goes away permanently, but rheumatoid arthritis in adults generally returns.
10. No. Medication, rest, exercise, heat, surgery, splints, walking aids and rehabilitation are all useful in arthritis treatment.
11. There is no evidence that climate affects the course of the disease.
12. Yes. The dose of aspirin sufficient to relieve pain may not be adequate to prevent joint damage. Regular doses of any medication, including aspirin, should not be taken without a doctor's supervision.

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National Forum

by Jim Dickinson

A season for renewal. You have to marvel at the amazing resiliency of our Republic, and its self-healing powers.

Just as all the news seems to be getting worse and worse, we seem to turn a corner, almost without noticing it, and some things that have been bothering us start getting repairs, and even improvements.

Oddly, a lot of this renewal seems to coincide with the presidential political seasons.

Every presidential election that comes along is—if you avert your attention from the candidates' frenzied glibness—accompanied at the grassroots by work that's apparently coincidental, and largely unnoticed, on formerly ignored problems.

Take some of pharmacy's problems, for example. Just as some of them seem to be worse than ever (dispensing physicians, mail-order), others seem to be undergoing cyclical repair in this political season (curriculum changes in the schools, legal decisions bearing on liability, freedom-of-choice reforms, fiscal incentives for pharmacists).

The liability issue is most instructive, because the law moves slowly and deliberately enough to be studied.

Pharmacists who have worried about recent legal decisions requiring them to counsel patients and to second-guess prescribers will be heartened by the recent reversal of one of those decisions (*Leesley v. West*, in Illinois). They will be even more heartened to know that this reversal is in line with a trend in other recent cases which, in the view of such pharmacy law experts as West Virginia University's David B. Brushwood, recede from new liability burdens.

The *Leesley* case, it may be remembered, involved damages for severe gastrointestinal bleeding due to piroxicam (Feldene) in the absence of counseling by the pharmacist. The lower court faulted the pharmacist for not routinely dispensing the package insert.

The appeals court disagreed, ruling that (a) it would be an unreasonable burden on pharmacists and on manufacturers to require the dissemination of package inserts with every Rx, and (b) it is state policy not to expand the liability risks of health professionals.

This position, to some extent mirrored in a recent California State Supreme Court decision easing the tort liability of pharmaceutical manufacturers and a District of Columbia Superior Court decision discrediting the use of so-called "expert witnesses" who testify against health professionals for pay, has been 12 years in coming.

That is three presidential elections, for those whose memories do not reach back to the start of the current hyper-anxiety in pharmacy about liability.

If you step back from such admittedly important

pharmacy minutia as dispensing decisions, precise legal points, exact reimbursement amounts, and specific subjects taught in school, you see patterns and cycles in many of the things that impact the profession.

One is that at the end of the Nixon-Ford era, a new era for activism began (first for liberals and next, for ultra-conservatives), in which pharmacy was subjected to escalating cost-containment and legal liability ideas.

It wasn't alone, of course—all health professions felt the same assault at different times. The social conscience being expressed in this era that's now ending was probably this: Professionals who impact the most intimate conditions of the public at large have not been properly accountable, either in the way they do their work or in the way they charge for their services.

In suffering that assault under a variety of blunt legislative, regulatory and judicial instruments, those being wounded managed to make a few points, while adjusting their practices.

The first of these was the point that the work of saving money for programs is something that itself costs money, and should be paid for. Jimmy Carter's Federal Trade Commission eventually recognized this, and drafted a model substitution law that paved the way for today's imperfect "generic incentive" reimbursement mechanisms.

The other suffering that pharmacy did during the past 12 years got other points across, too. Among these was the idea that pharmacists know more about drugs than physicians do; this has been accepted in mandatory counseling laws in some states and, potentially, in the draft Medicare drug benefit bill, nationally.

And on the liability front, Professor Brushwood sees a see-sawing of legal principles during that period. Courts tested the old pharmacy excuse that dispensing carries with it no responsibilities to the patient or the prescriber, and found it not credible. Then, says Brushwood, they tested the idea that pharmacists have an enforceable duty to second-guess every prescription; recently, that too seems to have been found not credible.

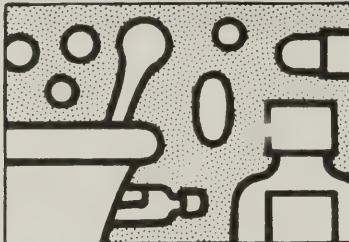
It's too soon to say what trends and patterns will form out of the current political season—or how long any of them will last. Just because we can look back in retrospect and see certain gains in pharmacy within the framework of a 12-year political era does not necessarily mean that another 12-year era is beginning.

But in this political season, while our attention may be distracted by personalities and rhetoric, it should be helpful to consider the evidence that this is also a time when real problems tend to get sorted out—even if they aren't fixed with a satisfying click.

At first glance it might not look like it, but away from the television cameras this is the season for renewal.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Things You Should Know FOR YOUR GOOD HEALTH



Calcium and Osteoporosis . . . Diet or Supplementation?

Dietary consumption of calcium is currently the subject of much discussion. Indeed, calcium-containing products are receiving bountiful ink in the health care press as well as increased advertising attention. One of the reasons for this seemingly new interest in an age old element is calcium's suspected role in osteoporosis.

Osteoporosis, a bone (osteoporosis) condition characterized by porosity (porosis), depletes bone mass. Commonly known as "Brittle Bone Disease", osteoporosis does not appear to change the chemical composition of the bone, but decreases the amount of bone tissue leaving the bones fragile and susceptible to fracture.

Most of us have seen the effects of osteoporosis. It is often apparent as a curvature of the back (known as Dowager's hump) triggered by osteoporosis causing the bones of the spine to fracture. After several years the stricken individual is left "hunched forward." In this country these types of fractures are thought to affect, to varying degrees, as many as one-fourth of all women 60 years old or more.

Some researchers contend that prevention of osteoporosis can be achieved through maintaining a proper diet with adequate levels of both calcium and vitamin D, and a regular schedule of exercise.

Vitamin D is necessary because it aids in the absorption of calcium from the intestine into the blood stream.

However, more recent scientific evidence suggests that the female hormone estrogen may play a significant role in the prevention of osteoporosis. Estrogen, among other functions, assists in the formation of bone tissue. The decrease of this hormone in post-menopausal women may help to explain the significant incidence of osteoporosis in this age group as opposed to the rest of the population.

Therefore, assuming that you are a healthy person, getting adequate exercise, and your diet supplies you the recommended daily allowance (RDA) of calcium (800 mg), you most likely do not need supplementation. The problem is that a large segment of the population does not maintain such a diet and consequently may need to take a calcium and/or vitamin D supplement.

Also, women approaching the menopause years and those that are post-menopausal should ask a physician about their propensity toward osteoporosis.

For more information about calcium and osteoporosis **ASK YOUR PHARMACIST**. It's For Your Good Health.

This continuing feature of *The Maryland Pharmacist* is brought to you by the MPhA Committee and Public Relations and Consumer Affairs. The Committee encourages all pharmacists to detach and duplicate sufficient quantities to dispense with medications this month. For more information on written patient information education materials, contact the MPhA office's Department of Professional Affairs at (301) 727-0746.

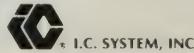
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MPhA's New Executive Director



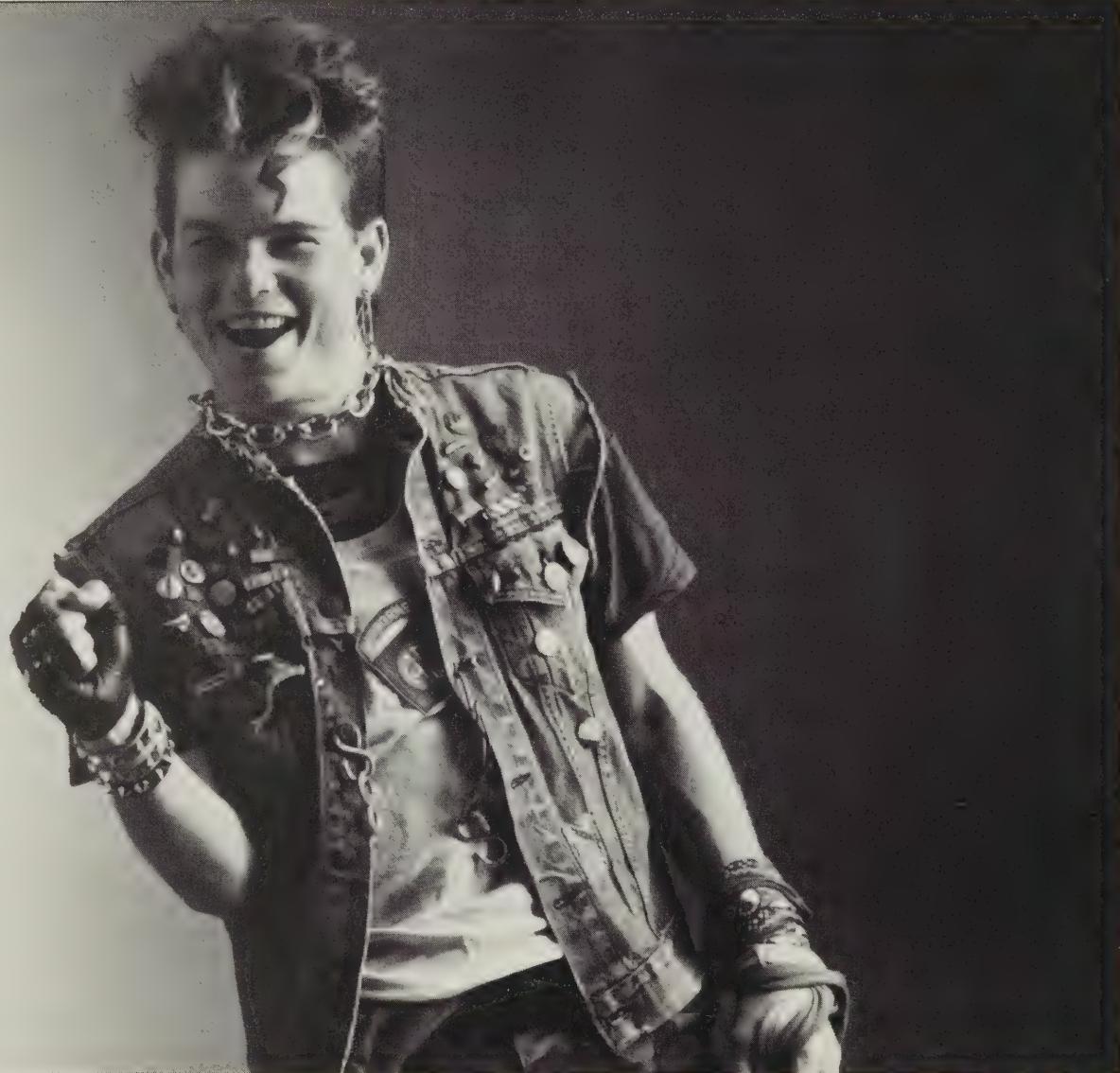
Gregory Wood, P.D., J.D. has accepted the position of MPhA's Executive Director. Greg will take over the job on August 1, 1988. Both a pharmacist and an attorney, he comes to us from his position as Executive Director of the Missouri Pharmaceutical Association.

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THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

LAMBDA KAPPA SIGMA sorority is planning its 75th Anniversary, August 2-6, 1988 at the Copley Plaza Hotel in Boston. All LKS sisters are encouraged to come and celebrate the future of LKS and women in pharmacy. For details, contact Mary Greer at Lambda Kappa Sigma, P.O. Box 981, Claremont, OK 74018.

SPECIAL SEMINAR PLANNED on "Teaching People with Low Literacy Skills: A Workshop for Health Professionals" for April 14, 1988, 8:30 a.m. to 4:00 p.m. at the Lord Baltimore Hotel. For registration information, contact Phyllis Wood, R.N., M.P.H. at 532-3838.

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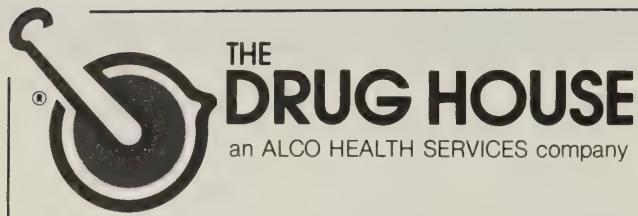


Next Month. . . .
All the *HOT* legal and
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calendar



- June 5 (Sun.)—CECC—Substance Abuse Among Pharmacy Staff
- June 5-9—ASHP Annual Meeting—San Francisco
- June 12 (Sun.)—AZO Installation Dinner Meeting
- June 19-23—MPhA CONVENTION—SHERATON OCEAN CITY—RESERVE YOUR SPOT IN THE SUN
- Oct. 21 (Fri.)—MSHP Annual Seminar—Sheraton Ocean City, Md.



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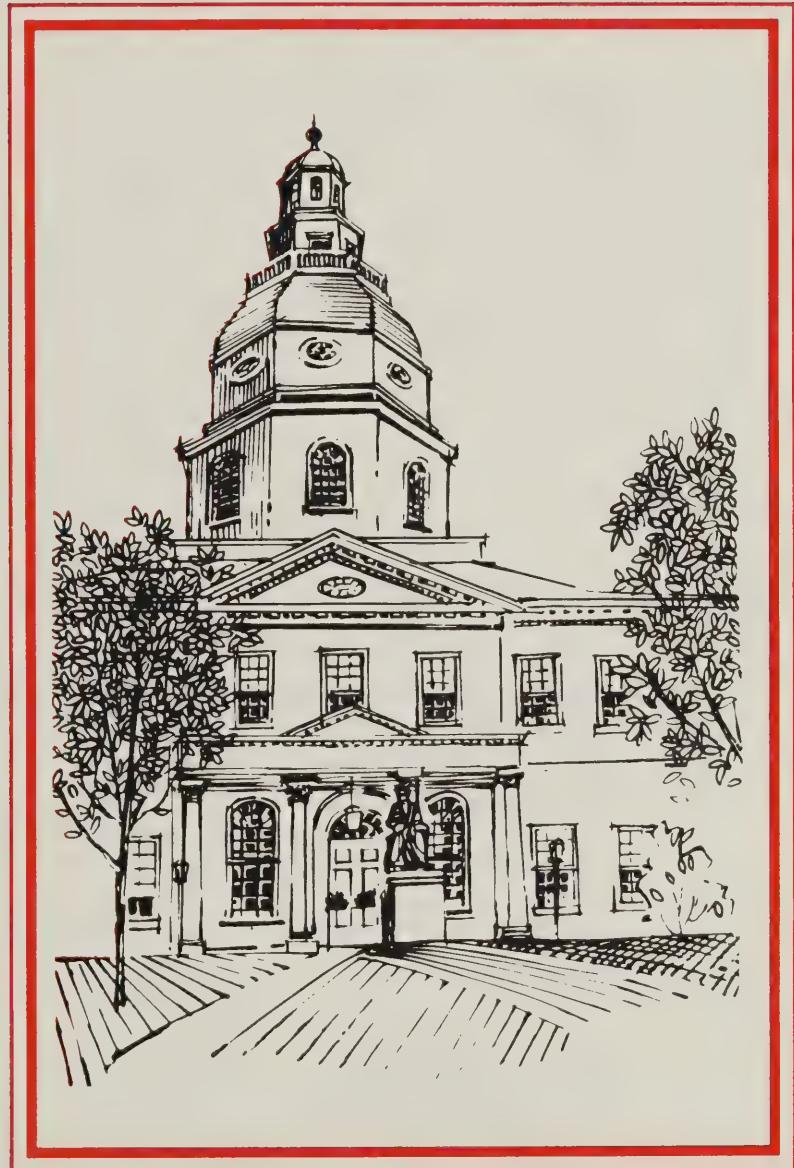
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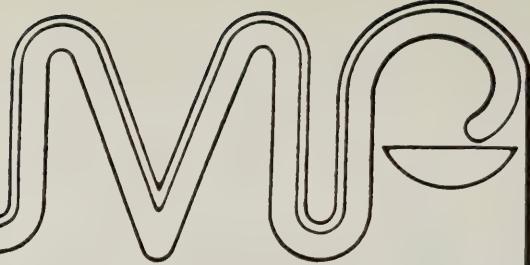
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*The Challenge Behind . . .
The Challenge Ahead . . .*

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JULY, 1988

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Commentary

I am very pleased to be installed as President of the Maryland Pharmacists Association for the coming year. I will be working with an exceptional Board of Trustees consisting of two hospital pharmacists, 6 community pharmacists, three chain pharmacists, and three consultant pharmacists. Never before has the diversity of our membership been so well represented. Attending our monthly Board meetings we have a member of the faculty of the school of pharmacy, a member and staff of the Board of Pharmacy, and Paul Jeffrey, president of the Maryland Hospital Pharmacists Association. These dedicated professionals are making pharmacy happen in Maryland.

And are things happening! Third-party control and payment problems . . . doctors dispensing for a profit . . . mail order drugs . . . pharmacy technicians seeking regulatory recognition and formal education . . . closed HMOs inhibiting freedom of choice . . . the list seems endless. As president, it is my goal to see that these obstacles are met head-on and overcome by MPhA. I pledge to increase the value of our Association to all Maryland pharmacists by seeing that we address many of the specific needs of our membership. One personal goal I have is to provide more high quality continuing education programs to increase every pharmacist's professional knowledge and standing.

I invite each of you to actively participate in your MPhA by voicing your concerns. With progressive leadership, newly elected officers, strong committees, well informed members, and a dedicated office staff we will all have a year to remember.

Elwin Alpern, P.D.

President

Continuing Education

Advising Consumers on the Use of OTC Antihistamines



Gossel



Wuest

by Thomas A. Gossel, R.Ph., Ph.D.

Professor of Pharmacology

and Toxicology

Ohio Northern University

Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.

Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. acquaint pharmacists with the indications for antihistamine therapy; and
2. explain the actions and reactions, differences and similarities of various antihistamines.

Objectives

At the conclusion of this lesson, participants will be able to:

1. identify major chemical classes of antihistamines and cite examples from each class;
2. demonstrate an understanding of the physiologic role of histamine and the types of conditions that are self-treatable with OTC antihistamines;
3. choose from a list of products, the one that should be dispensed when a specific antihistamine, or activity, is desired;
4. exhibit knowledge of the adverse reactions and toxicity associated with antihistamines; and
5. select points of information to pass along to consumers who inquire about antihistamines.

Since the pioneer antihistamines pyrilamine and diphenhydramine were introduced into clinical therapeutics four decades ago, Americans have maintained a love affair with this class of pharmacologic agents. Dozens more have been marketed since and still more are on the way.

This lesson describes the body's physiologic response to histamine. It elaborates on the actions and reactions associated with antihistamines, and identifies specific medical conditions that are self-treatable

with antihistamines. It also provides information on the similarities and differences between the various products that pharmacists need to know when counseling consumers on the choice of an appropriate drug for a specific purpose.

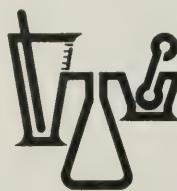
Review of Histamine and Antihistamines

The term histamine was coined from the Greek stem *Histos*, meaning tissue. It is a biogenic amine that is distributed throughout the body. Histamine is synthesized and stored in mast cells in tissues, and in basophils in blood. It is also stored in other cells in the skin, brain, gastric mucosa, and in many rapidly growing tissues.

While mast cells are located throughout the body, they are present in the eyes and nose in relatively large concentration. The number has been determined to be 200 to 400/mm³ tissue in the nose, and 500/mm³ in the conjunctiva. This explains why nasal and ocular tissues are especially susceptible to allergic reactions.

In its free form, histamine binds with and activates specific configurations on cell membranes known as histamine-1 (H₁) or histamine-2 (H₂) receptors. Both are distributed throughout the body. When stimulated, H₁ receptors are associated with vascular dilation, edema, and the inflammatory process. Their activation is also the cause of the "allergic response." A high concentration of H₂ receptors are located on the walls of parietal cells in the gastric mucosa. When these are stimulated, increased hydrochloric acid is released into the stomach.

The Allergic Response. Histamine elicits a characteristic reaction known as the "triple response." This consists of a localized red spot at the



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site of release that appears within a few seconds, and extends outward for a few millimeters. The spot soon takes on a bluish appearance. A "flare," or brighter red flush, spreads another centimeter beyond the original red spot. Within 1 to 2 minutes, a wheal appears at the original spot. The first two responses result from direct and reflex action to dilate minute blood vessels. The wheal appears because of increased vessel permeability, which allows loss of fluid into the interstitial area, and thus, edema. Histamine also stimulates exocrine gland tissue resulting in the runny nose, and watery and itchy eyes of hay fever and colds.

A number of other physiologic substances, in addition to histamine, are also involved in the allergic response, and are released along with it from mast cells and basophils. These include serotonin, heparin, an eosinophil chemotactic factor, a neutrophil chemotactic factor, leukotrienes and various proteolytic enzymes.

Antihistamines are believed to block only histamine. These other substances may be much more powerful than histamine, but remain unopposed.

Antihistamines

More than 50 separate chemical entities have been developed and marketed as antihistamines. Approximately one-half have survived and, at the time of publication of this article, about a dozen are available OTC. Table 1 lists currently marketed single-entity antihistamines by class.

Following the concept of histamine receptors, antihistamines are classed pharmacologically as H₁ or H₂ antagonists. While knowledge of their actions continues to evolve, it is thought that H₁ antagonists competitively block peripheral histamine action and H₂ antagonists block histamine action on parietal cells. Although histamine is the common agonist, histamine antagonists are specific for their respective receptor types. This lesson focuses on H₁ antagonists, and the term antihistamine will refer to these drugs.

Antihistamines are readily absorbed from the gastrointestinal tract. Activity is usually achieved within 30 minutes, is maximum by 1

| Table 1 | |
|---|--|
| Antihistamine Classification | |
| Alkylamines | |
| †Brompheniramine maleate | |
| †Chlorpheniramine maleate | |
| †Dexbrompheniramine | |
| †Dexchlorpheniramine maleate | |
| †Triprolidine hydrochloride | |
| Ethanolamines | |
| Carboxinamine maleate | |
| Clemastine fumarate | |
| *†Dimenhydrinate | |
| †Diphenhydramine hydrochloride | |
| †Doxylamine succinate | |
| Ethylenediamines | |
| †Pyrilamine maleate | |
| Tripeleannamine | |
| Phenothiazines | |
| Methdilazine hydrochloride | |
| Promethazine hydrochloride | |
| Trimeprazine tartrate | |
| Piperazines | |
| *†Cyclizine hydrochloride | |
| Hydroxyzine hydrochloride | |
| Hydroxyzine pamoate | |
| *†Meclizine hydrochloride | |
| Miscellaneous | |
| Azatadine maleate | |
| Cyproheptadine hydrochloride | |
| Diphenylpyraline hydrochloride | |
| †Phenindamine tartrate | |
| Terfenadine | |
| †Available OTC | |
| *OTC use for prevention and/or treatment of motion sickness | |

to 2 hours, and persists 3 to 6 hours. The long-acting piperazine derivatives and terfenadine have a duration of action of 12 to 24 hours.

The drugs are metabolized by hepatic microsomal enzymes. They stimulate their own metabolism by inducing the activity of involved enzymes. Thus, tolerance with reduced therapeutic response to antihistamines may develop following continued administration.

Recommending OTC Antihistamine Drugs

Over-the-counter antihistamines have been ruled to be effective in treating symptoms of hay fever and colds. Good results have also been obtained in treating conjunctivitis and seasonal rhinitis. An FDA/OTC advisory panel concluded that the

drugs are effective in treating the specific symptoms of itchy, watery eyes due to hay fever or other upper respiratory allergies, and runny nose and itchy, sore throat. Antihistamines have also been shown to be effective in treating symptoms of the runny nose and sneezing associated with the common cold (Table 2).

Allergic Rhinitis. For treating allergic rhinitis (hay fever) chronically suffered by 17 million Americans, the drugs are most effective early in the season when pollen counts are lowest. Later, as the pollen concentration increases and allergy-induced histamine release is excessive, the allergy sufferer may not continue to obtain adequate relief. To be effective, antihistamines must enter into and combine with the histamine-specific chemical receptors on the membrane of cells sensitive to its stimulation. This is a dynamic, ever changing situation whereby the antihistamine and histamine are competing for the same receptor sites. Relative concentrations of each determine which will predominate. Therefore, if the antihistamine is present in high enough concentration when the initial surge of histamine is released by the allergic response, symptoms should be reduced or ameliorated.

Common Cold. Antihistamines have been used, almost since their discovery, for treating symptoms of the common cold. Until recently, however, reports suggesting a positive benefit of antihistamines in alleviating common cold symptoms were largely based on subjective patient impressions rather than controlled clinical investigation.

However, controlled studies with chlorpheniramine have shown that it is significantly more effective than a placebo in alleviating symptoms of runny nose and sneezing associated with the common cold. Since the pharmacologic actions of the various antihistamines are similar, it is generally believed that other antihistamines are equally as effective.

Symptoms of allergic rhinitis (sometimes incorrectly referred to as a "summer cold") are similar to and overlap those of the common cold. Although consumers may be confused about the correct name, treatment is similar. Table 3 presents information differentiating the com-

Table 2**FDA-Approved Indications for Antihistamines**

| Prescription* | Over-the-Counter** |
|--|--|
| Allergic conjunctivitis | Temporary relief of symptoms of the common cold |
| Allergic reactions to blood or plasma | |
| Anaphylactic reactions (adjunctive to epinephrine) | Hay Fever symptoms: |
| Dermographism | <ul style="list-style-type: none"> • itchy nose • itchy throat • itchy, watery eyes • runny nose • sneezing |
| Localized angioedema | |
| Parkinsonism | |
| Perennial allergic rhinitis | |
| Seasonal allergic rhinitis | |
| Urticaria | |
| Vasomotor rhinitis | |

*Not all antihistamines are indicated for all conditions/symptoms.

**Some OTC antihistamines are also indicated as antitussives, antiemetics and sleep aids.

mon cold and allergic rhinitis.

Local Effects. Antihistamines possess a local anesthetic action on dermal sensory receptors. They are therefore used topically to relieve pain and itching resulting from the allergic response (e.g., from poison ivy and oak, and insect bites and stings). Their local histamine-blocking action *per se* does not contribute significantly to such therapy. Rather, it is their local anesthetic effect that inhibits the passage of pain impulses to the brain. When itching is widespread, antihistamines are more effective taken orally.

Antihistamine Safety

Most adverse effects to antihistamines are mild and disappear after several days of continued drug administration. But some persons may be so strongly affected that they discontinue drug administration rather than suffer its consequences. Drowsiness and anticholinergic activity are two such effects that reduce patient compliance.

Most antihistamines are highly lipid soluble and readily cross the blood-brain barrier to enter the CNS. The adverse effect common to most antihistamines is drowsiness.

As stated previously, histamine is a biogenic amine, meaning it is a neurotransmitter as well as a hormone. In the brain, histamine is partly responsible for alertness and wakefulness. Therefore, antihistamines that block histamine receptors

decrease wakefulness and cause drowsiness.

Antihistamines that exert the most marked drowsiness are ethanolamines and phenothiazine derivatives, followed by the ethylenediamines and piperazines. The alkylamines have little effect. Terfenadine (Seldane), introduced to the American market on prescription-only status (because that is the way new drugs must be introduced and remain until proven safe for OTC use), does not significantly enter the CNS. Therefore, it does not cause drowsiness in most persons.

Concurrent administration of other depressant drugs, including alcohol, enhances drowsiness. Individuals should, therefore, avoid concurrent therapy with alcohol and

other depressant drugs, as well as other antihistamines. Additionally, some antihistamines possess significant central anticholinergic and alpha-adrenergic receptor blocking actions which could contribute to drowsiness.

This anticholinergic activity may also pose potential hazards to persons with chronic obstructive pulmonary diseases such as asthma and emphysema, acute narrow angle glaucoma or enlarged prostate. The potential problem with pulmonary disease is that anticholinergics reduce respiratory secretions, causing them to be more viscous and difficult to expectorate, thus aggravating the condition. With narrow angle glaucoma, anticholinergics can further inhibit the outflow of aqueous humor and worsen the intraocular pressure. In enlarged prostate, its physical size added to the urinary retention caused by anticholinergic activity of antihistamines makes urination more difficult.

Antihistamines can exert additive effects with other anticholinergic drugs. Monoamine oxidase inhibitors can prolong and intensify both the CNS depressant and anticholinergic effects of antihistamines.

As with other adverse effects, drowsiness frequently decreases in severity after several days of therapy. If it is particularly bothersome or persists, switching to an antihistamine of an alternate chemical class may be beneficial. Or, the consumer may be counseled to contact a physi-

Table 3

| Differentiating Between the Common Cold and Allergic Rhinitis | | |
|---|---|--------------------------------|
| Symptom/Point | Common Cold | Allergic Rhinitis |
| Inciting cause | Virus | Allergen |
| Cough | Common, especially in latter phase | Uncommon |
| Fever | Rare | Absent |
| Itchy nose and eyes | Occur | Common |
| Nasal congestion | Common | Common |
| Nasal Discharge | Mucopurulent; occurs especially during days 1-3 | Watery, common; occurs anytime |
| Pruritus | Uncommon | Common |
| Sneezing | Uncommon | Common |
| Watering and redness of eyes | Common | Common |
| Occurrence | Anytime | Seasonal |

cian and inquire about the prescription drug terfenadine.

All things considered, antihistamines have a wide margin of safety when properly used. Nonetheless, they can cause accidental poisoning, especially in children. Their widespread availability in households adds to this potential.

Children who ingest antihistamines often become excited instead of sedated. This is because their central inhibitory centers are not fully developed. When these underdeveloped centers are inhibited by antihistamines leaving excitatory neurons predominating, CNS stimulation (resulting in ataxia, hallucinations and seizures) can occur leading to coma, circulatory collapse and respiratory failure.

Overview

The literature contains conflicting claims for antihistamine use. When counseling consumers on the selection of an OTC antihistamine, it should be realized that antihistamines will not cure the common cold or hay fever, but they should alleviate histamine-induced symptoms in most individuals. Because people differ biologically, there is some variation in individuals' response to a particular antihistamine product. Oftentimes, trying a product containing different active ingredients is the best method for determining what is best for any one individual.

By sharing their knowledge with consumers, pharmacists can play a major role in helping consumers select antihistamine products. This is also a good way to maintain and possibly increase their current share of OTC antihistamine product sales. Table 4 contains specific advice for consumers relative to OTC antihistamine products.

Persons who self-medicate with antihistamines for relief of allergic symptoms may decide to take the medication only when their symptoms are intolerable. Then, as soon as they feel better, they discontinue the medication. As stated earlier, this is not the correct method for taking antihistamines, and all too often the product is incorrectly faulted for failing to provide continued relief.

When taken on occasional basis, antihistamines impart some, but not adequate, therapeutic action due to their anticholinergic activity. If maximal relief of symptoms is desired, antihistamines should be taken continuously throughout the season of the offending allergen, rather than sporadically. When antihistamine therapy must be maintained over an extended period of time, a controlled-dosage release product, or one with an inherently long duration of action can enhance patient compliance. The most effective use of antihistamines is to find the agent that works best and take it appropriately.

An FDA/OTC advisory panel that reviewed these agents found that taking subtherapeutic amounts of several antihistamines is less effective than taking the full amount of the correct antihistamine, and at the

same time, exposes the person to possible sensitivity reactions to the individual ingredients. Therefore, FDA will allow marketing of OTC products that contain only one antihistamine.

Persons suffering from allergic rhinitis or other allergies should avoid contact with the offending allergens. This may be relatively simple when a single, known allergen is involved. But allergens such as grass, tree and weed pollen may be impossible to completely avoid. Using an air conditioner with an air purifier attached in the spring and summer months, and keeping the doors and windows closed whenever possible, can help sufferers reduce exposure. Homes should be thoroughly vacuumed and cleaned regularly to reduce dust and mold concentrations.

Consumers may ask why some antihistamine products are available

Table 4
Consumer Information for OTC Antihistamines

- Do not take this product if you have asthma, emphysema or other chronic pulmonary disease; shortness of breath or difficulty in breathing; glaucoma; or have difficulty in urination due to enlargement of the prostate gland, unless your doctor advises and supervises you.
- This product may cause drowsiness. Avoid alcoholic beverages and other drugs which also cause drowsiness while taking this product. Use caution when driving a motor vehicle or operating machinery.
- This product may cause excessive excitability and sleeplessness in children. Do not give it to children under 6 years of age unless your doctor advises and supervises you.
- Do not take products containing phenindamine immediately before going to bed. They may cause nervousness and insomnia in some individuals.
- Do not take this product if you are taking antidepressant or anti-Parkinson medication unless your doctor advises and supervises you.
- Take this product with food or milk if it upsets your stomach.
- This product may cause your mouth to feel dry. If this occurs, suck on ice chips or sugarless candy, or chew sugarless gum. Your pharmacist can also help you select an OTC artificial saliva product if your mouth is uncomfortably dry.
- On days when pollen counts are particularly high, shampooing your hair and bathing before bedtime may help you sleep better.
- If you are taking this product for a seasonal allergy, you must take it for the entire length of the season in which the particular allergen prevails. Your doctor or pharmacist can help you determine this time.
- As with all drugs, if you are pregnant or nursing a baby, contact your doctor for advice before using this product.
- Keep this and all drug products out of the reach of children.

for self-administration, whereas others require a prescription to purchase. This is an especially difficult question to satisfactorily answer when both products contain the same ingredients and perhaps the same dosages.

Prescription products such as Benadryl 50 mg Kapsules are labeled for treatment of conditions such as angioedema, dermographism and blood transfusion reactions (see Table 2). Benadryl 25 mg capsules (OTC) are labeled for relief of symptoms that can be self-treated. Therefore, the difference is in the manufacturer's labeling, not the ingredient. 



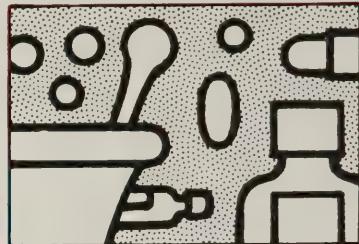
ASCP Reinvents the Wheel

The American Society of Consultant Pharmacists announces the release of its newest publication—a wheelchart entitled, "Drugs That Should Not Be Chewed or Crushed."

The magnetic wheelchart can be displayed on medication carts in nursing homes for quick reference. In an easy-to-read format, it provides current information, with alternatives and comments for drugs which should not be chewed or crushed.

For more information, contact ASCP headquarters at 2300 Ninth St. South, Suite 515, Arlington, VA 22204.

Things You Should Know FOR YOUR GOOD HEALTH



Sun, Fun, and Medications

Spring and summer find many of us basking in the sunshine. However, too much outdoor seasonal fun may result in overexposure to ultraviolet radiation emitted by the sun. The result? You guessed it — sunburn. Care should be taken to limit the amount of time our skin is exposed to the sun's rays and to liberally use sunscreens.

Sunburn is a self-limiting problem. That is, once a sunburn occurs, if you avoid further contact with the sun, the sunburn will go away. Unless a sunburn is quite severe or covers a significant portion of the body (10% for children and 15 to 20% for adults), professional medical treatment is not necessary.

Of special concern to health professionals is patients taking medications which cause them to be extra sensitive to the sun's effects. Sunburns that appear to be greater than that which would be expected, are called photosensitivity reactions. Drug-induced photosensitivity reactions can occur from the use of topical medications — such as creams and ointments — or systemic medications — for example, those swallowed or inhaled.

Generally, two types of photosensitivity reactions occur, photoallergies and phototoxicities. Photoallergies most often occur from the use of topical preparations. The symptoms of such reactions appear as non-localized rashes and other skin eruptions. That is, a rash may appear on parts of the body not exposed to the sun. Phototoxicities, on the other hand, more frequently occur when certain medications are taken internally. A seemingly over-exaggerated sunburn is an indication that you may be experiencing a phototoxicity reaction caused by medications. This reaction is usually localized to those areas directly exposed to the sun.

What can you do about the potential inconvenience caused by drug-induced photosensitivity reactions? To begin with, anyone taking or applying medications should be thoroughly informed about that drug's potential to cause such reactions; not all medications cause this problem. Your family pharmacist is the best source for this information.

If you learn that your medication has a photosensitization potential, you should make a special effort to avoid prolonged exposure to the sun. This can be done by staying indoors or by using a "complete" sunblocking agent on the skin. Sunblocks come in various forms, including lotions, creams, gels, and sticks. The active ingredient in these products is a chemical called PABA (para-aminobenzoic acid). The higher the concentration of PABA, the more blocking protection the product will provide. Commercially available products carry numbers on them (from 2 to 25) to describe their PABA concentration and, therefore, their protection power. For example, a product with a number "2," will provide twice the protection of the skin without the product. A product carrying a "15" will afford fifteen times the body's normal protection and is considered to be a "complete" blocking agent.

Some people have jobs and lifestyles which makes staying indoors or using sunblocks impossible. If you are one of these people, ask your physician to consult with your pharmacist to find an alternative medication that would pose less of a photosensitivity risk. It is important to remember though, that medication alternatives are not always available. If photosensitivity is a problem for you, ASK YOUR PHARMACIST for assistance. It's For Your Good Health.

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Continuing Education

The final regulations requiring continuing education for all Maryland pharmacists will be adopted sometime this month. Here are these regulations. Make special note of Section D, sub-section 7 which explains how the regs affect your license.

10.34.18 Continuing Education for Pharmacists

.01 Scope

These regulations govern any person who desires to renew a license to practice pharmacy in Maryland.

.02 Requirements for Pharmacists Practicing in Maryland.

A. A pharmacist licensed to practice in Maryland applying for renewal shall earn 30 hours of approved continuing pharmaceutical education within the 2-year period immediately preceding the licensee's renewal application.

B. A pharmacists shall attest to the fact that the pharmacist has completed the continuing pharmaceutical education requirement on a verified form. The licensee shall retain supporting documents for inspection by the Board for 4 years after the date of renewal for which the continuing education credits were used.

C. The continuing pharmaceutical education requirement shall apply to all renewal applications subsequent to the first renewal.

.03 Requirements for Pharmacists Not Practicing in Maryland.

A pharmacist not practicing in Maryland shall fulfill the continuing education requirements of one of the following boards of pharmacy in order to renew a Maryland license:

- A. Maryland;
- B. The state where the pharmacist is practicing; or
- C. The state where the pharmacist resides.

.04 Requirements for Pharmacists who are Authorized Prescribers.

A pharmacist who is also an authorized prescriber licensed by a board (in Maryland or another state) that requires continuing education (CE) may meet the Board's CE requirements by fulfilling the CE requirements of any board which licenses the pharmacist as an authorized prescriber.

.05 Responsibility for Accrediting Programs.

The Board of Pharmacy shall establish a committee to evaluate continuing pharmaceutical education programs and approve programs and providers.

.06 Accredited Continuing Education Providers.

A. The following providers are approved for any programs they offer which otherwise qualify for CE credit:

- (1) American Counsel on Pharmaceutical Education (ACPE);
- (2) Maryland Pharmaceutical Association (MPHA);
- (3) Maryland Society of Hospital Pharmacists (MSHP);
- (4) All schools of pharmacy accredited by ACPE;
- (5) Out-of-state providers approved by a state board of pharmacy;
- (6) Other accredited colleges and universities offering programs approved by the committee;
- (7) Food and Drug Administration (FDA); and
- (8) Drug Enforcement Administration (DEA).

B. Procedures for Approval of Additional Providers. Other providers shall initially request approval for individual programs. After a provider has received approval for programs for a 2-year period, the provider may apply for approved provider status for an additional 2-year period. If approved provider status is received, no approval is necessary for individual programs. Approved providers may request renewal of this status every 2 years.

C. All providers of continuing education shall furnish a certificate of completion to all participants who qualify. The provider shall include the:

- (1) Name of the participant;
- (2) Name of the provider;
- (3) Description of course work;
- (4) Number of hours;
- (5) Date of completion;
- (6) Program identification number or provider number on the certificate.

D. The Committee may suspend or revoke approval of a continuing education provider if it determines that the provider no longer meets the requirements of Health Occupations Article §12-308.1, Annotated Code of Maryland.

.07 Miscellaneous.

A. Credits may not be carried over from one continuing education period to another.

B. For the first renewal period during which continuing education is mandatory for a pharmacist, all approved continuing education credits earned on or after July 1, 1986 will be accepted.

C. The Board of Pharmacy may grant an exception from the continuing education requirements if the pharmacist presents evidence that failure to comply was due to circumstances beyond the pharmacist's control.

D. For the first renewal period during which continuing education is mandatory for a pharmacist, the Board of Pharmacy will grant an exception from the 30 hours continuing education requirements. The Board will waive all continuing education requirements under this regulation for licenses being renewed September 30, 1988; and will waive 15 of the 30 hours of continuing education requirements for licenses being renewed September 30, 1989.

E. Falsifying continuing education records is grounds for disciplinary action under Health Occupations Article, §12-311(b)(1) and (2), Annotated Code of Maryland.

F. If the Board provides a form for information, the pharmacist shall use the form to supply the requested information to the Board.

GUIDELINES for Cosponsorship of a Continuing Education Program by the *CONTINUING EDUCATION* *COORDINATING COUNCIL*

The Maryland Pharmacy Continuing Education Coordinating Council (CECC) is an approved provider of continuing education by the American Council on Pharmaceutical Education (ACPE). The CECC reserves the right to accept or deny cosponsorship of specific programs on an individual basis. These guidelines must be followed by any group or organization seeking continuing education credit through CECC.

1. All requests for CECC cosponsorship must be made *in writing* to the CECC offices at 650 West Lombard Street, Baltimore, Maryland 21201. Requests should be made as early as possible in the planning process to allow for input by CECC. The identity, address, business and home phone numbers of the individual coordinating the proposed program must be submitted at the time the request is made.
2. In order to cover overhead and record keeping expenses associated with cosponsorship, the CECC will bill a charge for each program that CECC agrees to cosponsor plus a charge for each certificate issued.

3. The CECC will evaluate requests for cosponsorship using the ACPE's "Criteria for Quality."
4. In general, requests for CECC cosponsorship should be made only for programs which have pharmacists as the primary audience. Programs should be designed to be of significant interest to pharmacist audiences. A Pharmacist should be involved in the planning process to determine program content. Multi-disciplinary programs are acceptable if programming is of sufficient relevance to pharmacy.
5. Cosponsoring groups must provide to the CECC the justification for the topic selected. Ideally, the CECC prefers that a "needs assessment" be conducted.
6. To be considered for cosponsorship the following required information must be received 90 days (3 months) prior to the program's scheduled date. Requests received that fail to supply this information will not be considered for approval if less than 90 days remains before the program. Items with an asterisk (*) *must* be included on the final promotional pieces as well as on any drafts.

- * Program Title
- * Date, Time and Location of Program
- Program Coordinator
- * Sponsoring Organization (if any)
- * Program Summary, Purpose, and Learning Objectives
- * Program Schedule
- * Program Speakers (including degree, affiliation, and title)
Resumes of each speaker
- Target Audience and expected attendance
- Publicity/Promotion plans (include copies of *draft* brochures)
- Proposed Number of Continuing Education Units (CEU)
- * Registration Fee, if any
- * Written refund policy for cancellations, no-shows
Expected financial support/income other than registration fees
- Description of materials to be provided to Registrants
- Proposed Evaluation Forms:
 - Provider Evaluation
 - Participant Evaluation

7. The organization seeking cosponsorship shall be notified in writing when their request is approved/disapproved. CECC will assign the program a specific ACPE program number.

Continued . . .

This statement must appear with an ACPE logo on all promotional pieces:

The Maryland Pharmacy Continuing Education Coordinating Council is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education.

and followed by the assigned ACPE number and amount of continuing education credits as determined by CECC.

8. Within one week of the program, the following information must be submitted to the CECC offices.

Two copies of the program brochure

Copies of handouts and instructional materials

A list of names and addresses of pharmacists who completed the program

Program evaluations

Participant evaluations

9. The CECC will provide to participants, in a timely fashion, a certificate indicating satisfactory completion of the continuing education activity. CECC can provide CE credit only for those programs it cosponsors.
10. Any questions regarding CECC cosponsoring policy or these guidelines should be directed to the CECC, 650 West Lombard, Baltimore, Maryland 21201; or by calling (301) 727-0746.

Pharmacy Resource Book Available

(WASHINGTON)—The American Pharmaceutical Association (APhA), the national professional society of pharmacists, has published the first edition of Pharmacy Education and Careers: The APhA Resource Book.

The 88-page reference is designed for pharmacy students and others seeking specific information on a wide variety of pharmacy topics. Included is a listing of pharmacy schools, sources of scholarships and financial aid, an extensive review of training programs, a listing of pharmacy organizations and fraternities, state-by-state facts on board examinations and licensure, and guidelines for pursuing a career position in pharmacy.

The project was spurred by the 1986 Academy of Students of Pharmacy (ASP) Executive Committee, who pointed out that students need this information and must go to several different sources to get it.

The Parke-Davis Consumer Health Products Group, Warner-Lambert Company is the sponsor of the first edition of the APhA resource book.

The book is being distributed free to ASP members through the APhA ASP chapters or the book may be ordered for \$10 for APhA members, \$15 for non-members, by calling (800) 237-APhA.

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Our Lobbyist Reports 1988 Legislative Session Wrap-up

By: Robin Shaivitz
Registered MPhA Lobbyist

The 1988 General Assembly ended on April 11. During the 90 day session, I monitored 25 bills and the budget for 1989. Of those issues, I testified on 16 bills and the state budget for the Maryland Pharmacists Association. It was, indeed a busy year for pharmacy. For the first time, the Maryland Pharmacists Association sponsored a legislative breakfast in Annapolis. It was extremely well attended by members from around the state. Many of our Senators and Delegates attended as well. The highlight was the arrival of Governor William Donald Schaefer and Lieutenant Governor Melvin Steinberg. Both distinguished guests addressed our group and urged us to stay active and involved in the legislative process.

One of the most successful ventures that we participated in was a coalition with other health professional groups to work together to influence legislation that encouraged quality of health care delivery. We were instrumental in seeing some of our initiatives in that area pass. All of these bills dealt with health care services from Health Maintenance Organizations.

One of the surprises during the legislative session was a plan to increase the amount of co-payment for prescriptions for Medicaid and pharmacy assistance recipients. The Administration proposed in the budget to increase federal Medicaid from \$0.50 to \$2.00 for State-only Medicaid, from \$0.00 to \$2.00 for the rest, and Pharmacy Assistance from \$1.00 to \$5.00. In addition, the Administration proposed requiring all General Public Assistance (GPA) recipients living in Baltimore City and parts of Anne Arundel County to use a health maintenance organization as part of a managed care program. Maryland pharmacists mobilized to defeat these measures because we believed they would have a devastating effect on the poor as it pertained to health care delivery in general.

Certainly, we recognized that the costs of the Medical Care program in Maryland were sky-rocketing, but MPhA did not believe that the budget for the program should be balanced on the backs of Maryland pharmacists and the poor. First, we met with the newly-appointed Deputy Secretary for DHMH, Nelson Sabatini. He was very open to our suggestions of other ways to

reduce costs. Then, we testified in opposition to SB 375, the Maryland Pharmacy Assistance Program increases, and in opposition to that portion of DHMH's budget dealing with the increases in the Medicaid copayments and managed care. We were successful on both counts: 1) SB372 was defeated in the Senate Finance Committee and 2) Budget narrative was added to the fiscal year 1989 budget insisting that DHMH develop other alternatives for saving money. Further, the 2 budget committees as well as the Schaefer Administration, will be examining the Medical Assistance program beginning in May. They hope to be able to trim some of the costs without cutting necessary health services. Also, on May 10th, there will be a hearing on regulations for these changes in the Health Department. MPhA will be testifying in opposition to those regulations at that time.

The Maryland pharmacists were eager to see legislation pass this year that would have prevented third party payers from discriminating against pharmacy walk-in business as opposed to mail order pharmacy plans. House bill 435, sponsored by Delegate Casper Taylor, and its companion, Senate bill 377, sponsored by Senators Michael Wagner and Edward Kasemeyer, were designed to prohibit an insurer or health maintenance organization from waiving a co-pay for mail order business and insisting on a co-pay for the beneficiary or member who chose to get the prescription filled at a local pharmacy. The issue was one of fairness and freedom of choice. Unfortunately, the extensive opposition did not feel the same way. These bills were opposed by Blue Cross/Blue Shield, independent health insurers, the HMO Association, the Maryland Chamber of Commerce and organized labor. The chain drug stores took no official position, as their members were divided on a stance. Although there was the strong possibility that HB 435 could have passed the House Economic Matters Committee and perhaps the floor of the House, it was believed that it would be doomed to be defeated this year in the Senate. It was decided that our best strategy was to ask the Economic Matters Committee to study it during the summer and make some recommendations to "level the playing field" for the future.

If MPhA is to be successful, it is incumbent upon our organization to do the following:

- 1) develop a desired proposal for the Economic Matters Committee
- 2) monitor and participate, when appropriate, in the summer study

- 3) have constituent pharmacists contact members of the Economic Matters Committee and the Senate Finance Committee to let them know how much we need their support on this issue
- 4) develop a coalition of support from allied groups (Office on Aging, Seniors United, labor, other health professionals)
- 5) a summer study gives the Maryland pharmacists a golden opportunity to put its best foot forward and show the Maryland legislature that we are a strong organization of thoughtful professionals concerned with a productive business environment for our members as well as a responsive health care delivery system for all Marylanders.

Finally, one additional bill, SB 628—Health Occupations Boards—was a concern to us because its purpose was to set a fee structure for Boards that would more accurately reflect the costs of operating the Board. Unfortunately, the bill made the situation worse by allowing the Secretary of DHMH rather than the Legislature to set fees. We testified against this bill. The bill was “gutted” and there was still no guarantee that the fees collected by any one Board would go back to that particular Board. The only part of the bill that remained to be passed was a provision for the Board of Nursing, allowing that Board to adjust its schedule for collecting fees. We had no objection to this.

In summary, I think the session was a “mixed bag” in a year of transition for MPhA. We were successful about 50% of the time on issues of primary importance to the Association. I believe that we can raise our success ratio in the future with proper planning and participation among all our members. After all, there are very few organizations that can say they have a representative in every district across the State! I appreciate the confidence you placed in me during the past few months, and I look forward to our continuing to work together.

Long Term Care Conference

The Center for the Study of Pharmacy and Therapeutics for the Elderly is holding a one and one-half day invitational conference to explore current and future needs of long term care recipients and providers on July 19 and 20. Participants include health and social service providers from the public and private sector. A portion of this conference will be devoted to the needs for improved pharmaceutical services. The conference will be cochaired by Madeline Feinberg, Director Elder Health Program and Lucinda Maine, Ph.D. senior fellow of the center. Chancellor Brandt will provide opening remarks.

1988 LEGISLATIVE SEASON STATUS OF BILLS AFFECTING PHARMACY

| BILL/ACTION | PURPOSE |
|---------------------------------|---|
| HB 89 Withdrawn | To certify nurse midwives to prescribe certain drugs and devices. |
| HB 108 Withdrawn | Maryland Pharmacy Assistance Program changes in eligibility. |
| HB 110 Withdrawn | Protection of retail establishments from civil liability for public restrooms/toilet facilities. |
| HB 113 Defeated | Prohibition of smoking in public places. |
| HB 125 Defeated | Medical injury action standard of proof. |
| HB 162 Passed/ Amendments | Required licensing of PPO's with the state. |
| HB 169 Passed/ Amendments | Allowing Department of Health to delete drugs from the state formulary that pose a health risk to the public. |
| HB 240 Withdrawn | Resolution of HMO disputes. |
| HB 241 Passed | Resolution of complaints from patients and subscribers to HMOs. |
| HB 246 Withdrawn | Redefining the definition of cocaine (Housekeeping bill) |
| HB 345 Passed | Stock and surplus requirements for HMOs. |
| HB 347 Defeated | Protect providers of insolvent HMOs by allowing claims against controlling companies, organizations, or individuals controlling the HMO during its existence. |
| HB 435 Referred to Interim | Prevent health plans offering mail order prescription services from imposing co-payments on local pharmacy options only. |
| HB 532 Passed | Assessment of HMOs certificates of need. |
| SB 372 Defeated | Increase of Pharmacy Assistance copays to \$5.00 from \$1.00. |
| SB 377 Referred to Interim | Companion bill to HB 435. |
| SB 790 Passed | Companion bill to HB 246. |
| SB 516 No Action | Equal payment by 3rd parties for non-authorized providers. |
| SB 628 Passed/ Amendments | Allows Department of Health Secretary to set and control licensing fees for all health boards. Final bill affected Board of Nursing only. |
| HB 962 Defeated | Requiring HMOs to provide certain specialities for subscribers. |
| HB 1084 Defeated | Freedom of choice for allied health services for HMO subscribers. |
| HB 1161 Defeated | Companion bill to SB 372. |
| HJ 56 Defeated | To create a Task Force on the Interaction and Side Effects of Medications. |



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Senator Sasser and Representative Dorgan Target Mail Order

Senator Jim Sasser (D-TN) called for "more rigorous state and federal regulation of the mail order drug industry" at NARD's recent Annual Conference on National Legislation and Public Affairs. Sasser said that "we need to ensure that there is the highest possible standard of safety and soundness in the dispensing of prescription drugs, and I am convinced that that is not the case with many of the mail order houses."

A major concern cited by Sasser was the lack of accountability of mail order outfits. For instance, when a customer receives a "wrong prescription" from a mail order house, he or she is referred to a customer representative "who is not a registered pharmacist," and "often the plant that they're calling is in some distant state, thousands of miles away and enforcement actions against the offending personnel are very rare indeed."

Sasser referred to the August, 1987 hearings his Senate Governmental Affairs subcommittee held to investigate questionable practices by mail order drug outfits, saying that the hearings were prompted by "a great number of complaints about the quality of services received through federally supported mail order prescription plans." Sasser noted that during those hearings "we found some very startling evidence indeed about the quality of services that are rendered by some mail order prescription drug houses."

A major concern cited by Sasser was the use by mail order outfits of a "quota system for the filling of prescriptions." Three pharmacists who previously had worked at the mail order operation National Rx Services testified at the hearings, concealed by screens guarded by U.S. marshalls to protect their anonymity, and Sasser commented on the information they provided about the dangers of the quota system. For instance, "it was not uncommon in their rush to fill their quotas for incorrect prescriptions to be filled during the speed-up process and sometimes these prescriptions were actually sent out to the consumer."

A mail order mixup apparently caused the death this past January of a 70-year-old woman in Idaho, who died from a massive dose of Coumadin, a drug not prescribed for her and possibly sent by mistake by another branch of National Rx Services, the mail order subsidiary of Medco Containment Services, Inc. "Local authorities are still investigating the case," said Sasser.

Sasser said that during the August hearings "a panel of retail druggists testified quite eloquently how it's really common for elderly individuals to come to their local druggist for help after they have received incorrect or inappropriate prescriptions from the mail order houses." These elderly patients, said Sasser, "really have no place else to turn for help in order to check the prescription that they got from the mail order house, to set their own minds at ease, and to find out about their prescription needs."

Representative Byron Dorgan (D-ND) addressed other concerns about mail order practices. He maintained that it's time to "even up the score" on interstate mail order sales tax. In 1987, Dorgan proposed legislation (H.R. 1242) that would require mail order companies doing business in a state to comply with the same state and local tax laws as instate businesses. The Interstate Sales Collection Act has been reported to the full House Ways and Means Committee. Dorgan introduced the legislation because mail order houses "ought to be obligated to follow the same laws you do."

Key Members of Congress Criticize FTC Intervention

In remarks at NARD's Annual Conference on National Legislation and Public Affairs, Senator Albert Gore (D-TN) and Representative Tom Luken (D-OH) sharply criticized the Federal Trade Commission's "intervention" policy and expressed their support for legislation now in conference that would limit agency interference in state legislative and regulatory activities. Luken and Gore chair the House and Senate subcommittees with oversight of the FTC.

Instead of interfering with state legislative and regulatory initiatives, Luken said, the FTC should be enforcing the antitrust laws it seems to be ignoring. "The FTC just may have its priorities wrong," said Luken. "We're looking for real enforcement." Luken announced that he will introduce legislation clarifying the FTC's jurisdiction over commercial activities by nonprofits that use their tax-exempt advantage to compete with taxpaying businesses.

The FTC, said Gore, "has sought to serve as an instigator" in state legislative and regulatory activities, and insisted that "FTC should not interfere unless it is requested to do so." Pharmacy became concerned over FTC "intervention" activities when the agency committed on regulatory activities involving physician drug sales for profit in Georgia, Maryland, California, and other states. In opposing actions to regulate the

practice in these and other states and announcing its support for physician dispensing for profit, the FTC reversed its longstanding policy opposing the practice of physicians selling prescription drugs for profit—without any evidence to support its decision.

"The record is clear," said Gore in reference to all but the current FTC's opposition to physician dispensing, "and it has not been a partisan issue. I personally have grave reservations about this practice." All previous trade commissions have found the practice to be blatantly anticonsumer.

Gore, who chairs the Consumer Subcommittee of the Senate Commerce, Science, and Transportation Committee, cited promotional materials developed by drug repackaging companies to entice physicians into selling drugs, concluding that "we really have to take a dim view" of physician dispensing. "We could lose an important safeguard provided by pharmacists."

Gore urged pharmacists to strongly support passage of the FTC Authorization Bill, which contains language introduced by Gore and Luken that would require the commission to report to Congress well before it takes any action interfering with state legislative or regulatory activities and specifies that FTC may not comment on any such state activities unless it is requested to do so.

Luken also urged support for the FTC Reauthorization Bill, which has passed both the House and Senate and is currently in conference committee.

"I think the FTC is wrong on the merits on this issue," said Luken of the commission's aberrant position on physician dispensing for profit, noting that consumer groups support federal legislation that would prohibit the practice.

Luken is a member of the House Energy and Commerce Committee and chairs its Subcommittee on Transportation, Tourism, and Hazardous Materials.

While the current FTC says physician dispensing is procompetitive, said Luken, it ignores the "inevitable conflict of interest" in the practice, and has acted in an "audacious and fallacious" manner in its interference with attempts by states to regulate the practice.

Wake Up. . . .

You can't sit back and expect everybody else to take care of Maryland Pharmacy. Support PHARMPAC with your contributions today. Send contributions to: PHARMPAC, 650 West Lombard Street, Baltimore, MD 21201.

ASHP Opposes Advertising of Prescriptions

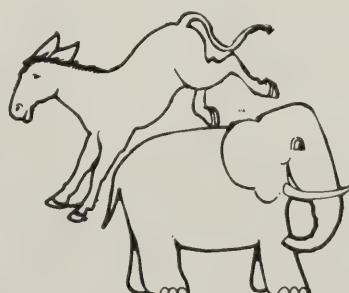
In a letter of May 3, ASHP Executive Vice President Joseph A. Oddis commended three Congressional committee and subcommittee chairmen for taking a strong stance in opposition to direct-to-consumer advertising of prescription drug products. Oddis noted that ASHP has long opposed such advertising practices, believing that they would undermine the physician-pharmacist-patient relationship that is critical to rational drug therapy.

"Prescription drug therapy is becoming increasingly complex," the letter states, "and providing complete information to the patient about the proper utilization, potential interactions, and known risks has never been more important." Such information must be provided through "the professional intervention of physicians and pharmacists" rather than advertisements in the mass media.

Other factors militating against direct-to-consumer advertising, the letter continues, are its potential effect on competition and drug costs. Prescription drug therapy should be based on the health-care practitioner's assessment of the drug's therapeutic advantages for a given patient. Widespread direct-to-consumer advertising might inevitably complicate such assessments by "subtly biasing the system in favor of those products with the biggest advertising budgets."

There is, the letter concludes, no disagreement on the need to find more effective ways of educating the public concerning safe use of prescription drugs. Direct-to-consumer advertising, however, lacks the objectivity that such educational efforts require. ASHP supports continued efforts by the Congress to seek to develop new educational methods that would "enhance patient understanding without jeopardizing patient care."

ASHP's letter was sent to John D. Dingell, Chairman, Committee on Energy and Commerce, Henry A. Waxman, Chairman, Subcommittee on Health and Environment, and Edward J. Markey, Chairman, Subcommittee on Telecommunications and Finance. Each has expressed strong opposition to direct-to-consumer advertising, most notably in recent letters to presidents of the three major television networks.



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AXID®

nizatidine capsules

Brief Summary. Consult the package insert for prescribing information.

Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within four weeks.

Axid is indicated for maintenance therapy for duodenal ulcer patients, at a reduced dosage of 150 mg h.s. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known.

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H₂-receptor antagonists.

Precautions: General—1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy.

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests—False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine.

Drug Interactions—No interactions have been observed between Axid and theophylline, chlorzoxazone, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxytic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement

compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, perinatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect, but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant human. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates. Although no studies have been conducted in lactating women, nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying duration. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported, it was not possible to

determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L), and in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H₂-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported.

Overdosage: There is little clinical experience with overdosage of Axid in humans. If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous LD₅₀ values in the rat and mouse were 301 mg/kg and 232 mg/kg respectively.

Axid® (nizatidine, Lilly)

Eli Lilly and Company
Indianapolis, Indiana
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Commentary

By Jim Dickinson

Pharmacy's acid test. One of the things I've always liked about pharmacy is that there's never a dull moment. For as long as I can remember, people have been saying, "Pharmacy's at the crossroads . . ." and then giving imperative advice, even ultimatums, to the profession as a whole.

The profession has never obeyed, mainly because it's composed of very individualistic individuals.

So here comes the latest crossroad: SERVICE. Or, rather, the lack of it. While pharmacy has always prided itself on the service it gives, everyone (including every pharmacist I ever met) takes it for granted.

It's the one edge that real, live pharmacists have over mail-order and dispensing physicians—free, friendly, convenient service, live and in person, just for the asking. Which side-effects to be prepared for, what other steps to take, which OTC to buy, when to (expensively) consult the physician.

Pharmacy service is always "free." By charging zero for it, pharmacists have unwittingly conditioned the community to think of it as being worth zero.

Along comes health cost-containment. This none-too-clever policy is controlled and operated by attitudes of pharmacy's own making—a whole new "network" that's alien to pharmacy.

This health-policy network is plugged-into by people who all have the same conditioning—that all you pay for in a pharmacy is the medical commodity plus profit (which may be too high).

Also plugged-in to this network are the fiscal heavyweights—the HMOs, Medicaid, Medicare, Aetna, the Blues, and others of that breed—plus get-rich-quick opportunists like the mail-order houses and dispensing physicians.

All of which tends to leave community pharmacy with nothing to do.

But into this awful crisis, along comes an exciting new defender: Highly automated, desk-top blood-level monitoring technology that's ideal for pharmacy use. It's developing at breakneck speed; in the estimation of FDA Commissioner Frank E. Young, the most sophisticated tests will be available for in-home use during the 1990s.

That, of course, means they will be available through mail-order. So the time to act is now—while the growing ranks of mobile people on maintenance therapy can still be imbued with the pharmacy habit.

The new-age tests need an investment of around \$3,700 (more or less), the courage to take a careful chance, and advertising help.

With a simple finger-stick, blood tests for theophylline levels (and a rapidly growing number of other drugs) can be conducted in minutes in the pharmacy, and charged for. On the basis of University of Arizona pharmacy school research, considering number of tests and other factors, a test may cost the pharmacy \$13 to perform, while the public is prepared to pay \$25 for it.

Insurance companies are now paying over \$90 for such tests, driven mainly by outmoded federal and insurance regulations that require these tests to be done in certified laboratories on the order of a licensed physician, with results reported to that physician.

But the new technology's desktop centrifuge-analyzers make such costs a rip-off.

They can bring into the pharmacy numerous blood tests for monitoring and adjusting the therapeutic ranges of theophylline, digoxin, carbamazepine, phenobarbital (and more to come), plus scores of other substances such as cholesterol, sodium, glucose, etc.

This has been successfully demonstrated with theophylline levels by the Arizona pharmacy school (professor of pharmacy practice J. Lyle Bootman, Ph.D., 602-626-5730), in a small chain community pharmacy.

Patients on sustained-release theophylline therapy had their medical histories and blood pressures taken in the pharmacy, and then a blood sample was drawn by a prick of a lancet.

The pharmacist or an assistant mixed 30 microliters of blood with distilled water to make an 800 microliter mix, a drop of which was added to a chemically impregnated paper strip. This, in turn was fed into a reflectance photometer (the study used a \$3,750 Ames Seralyzer, but others range from \$1,200 to \$15,000), which has a cassette programmed for each test type.

The machine reads the amount of color and codes it to the concentration of the drug. Patients are then counseled about their blood levels and how the drug works—a total time span of 10–15 minutes. They said the whole procedure was worth a \$25 charge.

In the Arizona experiment, test results were forwarded to the patient's physician for pharmacokinetic adjustments; Bootman says the next step will be pharmacokinetic adjustments by the pharmacist, but in most states this will require a change in the law.

State law would need to be consulted in any case, lest there be some hidden statute requiring all such tests to be done in expensive surroundings and under expensive professional procedures. The new technology has outstripped the basis for such laws, if they exist.

Continued . . .

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

If they don't, the only thing stopping a pharmacy from doing such tests is (a) liability fears and (b) local professional turfprotection. These amount to a simple, if big decision for the pharmacist: Do I have the guts to do it?

The automation of such tests minimizes the liability risk—but lawyers and insurance companies are skilled at frightening you. The question may be whether you have the courage to self-insure.

Eventually, of course, the insurance industry will discover the risklessness of this new technology, and the enormous cost savings, and premiums will encourage pharmacy blood tests.

But while pharmacists are waiting for that to happen, the technology itself will continue developing, becoming simpler and cheaper (like the digital wrist watch and VCR) until anyone at home will be able to get it all by mail.

In this age of commodity-drugs, I say it's an acid test for pharmacy. Right now.



APhA Executive Resident Selected

(WASHINGTON)—The American Pharmaceutical Association (APhA), the national professional society of pharmacists, has announced that Judy Shinogle has been selected as the 1988–89 APhA Executive Resident in Association Management.

Shinogle, from Wichita, Kansas, will receive a B.S. degree in pharmacy from the University of Kansas in May 1988. She received her B.A. degree in chemistry from the University of Kansas in 1985.

The residency is a post-graduate training program conducted at APhA and a selected state pharmacy association headquarters. The program, established as a tribute to former APhA President William S. Apple, is conducted by APhA in cooperation with the National Council of State Pharmaceutical Association Executives.

This one year program is designed to provide a quality, dual-site training experience to develop a pool of well qualified pharmacists to assume management positions in pharmacy-related organizations at both the state and national levels.

Shinogle is currently working as an intern at the Kansas Pharmacists Association, where she concentrates her activities on the Drug Utilization Review Committee and the state journal, and where she is also gaining a general knowledge of association work.

Continued from page 27.

- b. Coinsurance: The program pays a certain percentage (e.g. 80%) and the patient pays the remainder for all drugs.
- c. Copayment: The patient pays a fixed dollar amount out of pocket per prescription and is not reimbursed for this copayment.

Copayments, deductibles and coinsurance can be mixed together in a total program.

An Additional Proposal: Selected Coverage of Non Prescription Drugs

Non-prescription drugs are widely used in long-term care. In nursing homes, 40% of all drugs used are non-prescription drugs. Non-prescription drug use no longer depends on self-diagnosis. Indeed, the diagnosis of "pancreatic enzyme deficiency" must be made by a physician, who can then "prescribe" a non-prescription drug. Certainly, pain medications (acetaminophen, aspirin) have been found to be effective in mild to moderate cancer pain. Aspirin is, in patients not aspirin-sensitive, effective in the management of rheumatoid arthritis and osteoarthritis. Antacids, used in the treatment of active ulcers and prevention of recurring ulcers, are effective. Thus, in order to avoid costly prescription drug use, in cases where this may be possible, non-prescription drugs could well be used, more cost-effectively, if reimbursed.

Appendix

The following persons assisted in preparation of this report for the Center for the Study of Pharmacy and Therapeutics for the Elderly.

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Institutional Forums

CIPROFLOXACIN: THE FIRST SYSTEMICALLY ACTIVE ORAL FLUOROQUINOLONE

Thomas F. Turco

University of Maryland Medical System

Ciprofloxacin is an oral fluoroquinolone antibiotic structurally related to norfloxacin and nalidixic acid. It is more bioavailable than norfloxacin and achieves adequate serum and tissue concentrations to treat systemic infections. The drug is indicated for the treatment of lower respiratory tract, skin and skin structure, bone and joint, and urinary tract infections (UTI) and of infectious diarrhea (1).

Ciprofloxacin has in vitro anti-bacterial activity against a broad spectrum of gram-positive and gram-negative aerobic bacteria (2). It possesses excellent activity against Enterobacteriaceae such as *E. coli*, *Klebsiella*, *Enterobacter*, *Citrobacter*, and *Proteus* species. It is highly active in vitro against *Haemophilus influenzae*, *Branhamella catarrhalis*, and gonococci. It is active against *Pseudomonas aeruginosa* and *Staphylococcus* species, including methicillin-resistant *S. aureus* and *S. epidermidis*. Resistance has developed during ciprofloxacin therapy, particularly with *P. aeruginosa* and *S. aureus* (3,4). Many strains of streptococci, including *S. faecalis* and *S. pneumoniae* are only moderately susceptible to ciprofloxacin. Anaerobic bacteria are largely resistant to ciprofloxacin (5).

The safety and efficacy of ciprofloxacin has been demonstrated in the treatment of all of its FDA-approved indications. It is effective for some infections caused by pathogens which were resistant to penicillins, cephalosporins, and aminoglycosides (6). In patients treated for osteomyelitis, conventional parenteral antibiotic therapy is generally administered initially. Once stabilized, oral ciprofloxacin therapy may allow for earlier hospital discharge. In the treatment of UTI, ciprofloxacin should be reserved for infections caused by pathogens resistant to conventional therapy. To date, there are no comparative studies between ciprofloxacin and norfloxacin in the treatment of UTI due to *Pseudomonas*. Although currently not indicated, ciprofloxacin has demonstrated efficacy in treating chronic bacterial prostatitis (7). The drug has been used successfully for selective decontamination of the alimentary tract in patients with leukemia (8). An area of potential ciprofloxacin misuse is in the treatment of community-acquired pneumonia caused by *S. pneumoniae*. A penicillin or cephalosporin is preferred for treatment of streptococcal infections.

The most common adverse effects with ciprofloxacin involve the gastrointestinal tract (8%) and central nervous system (4%). Dizziness, headache, irritability, and rarely seizures have been reported. Ciprofloxacin and other quinolones are not recommended for use in children due to an association with arthropathy in immature animals (9). There has been a case report of arthropathy in a 16 year old patient with cystic fibrosis treated with ciprofloxacin (10). If arthropathy occurs during therapy, this agent should be discontinued promptly, as the reaction may be reversible.

Ciprofloxacin has been shown to increase theophylline serum concentrations (11). Careful monitoring and adjustment of theophylline are warranted. Aluminum or magnesium containing antacids may decrease ciprofloxacin absorption and should be administered one hour before or two hours after antibiotic doses. The usual dose of ciprofloxacin is 250–750 mg every 12 hours, depending on the type and severity of infection. With creatinine clearance less than 30 ml/min, dosage adjustment to every 24 hours is recommended (1).

Oral ciprofloxacin may represent cost-effective therapy after initial parenteral antibiotics for various infections. It may also allow some infections which required parenteral antibiotics in the past to be treated orally. The possibility of widespread misuse of this agent, the development of CNS toxicity, and the development of resistance to the drug warrant careful monitoring of ciprofloxacin prescribing in your institution.

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Community Forum

Business Tips for Pharmacy Managers/Owners

James R. Talley
School of Pharmacy
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Monroe, Louisiana

Business Questions: Free Answers from SBA

The Small Business Administration's Office of Advocacy has a free service called the "answer desk". The "answer desk" is operated weekdays from 9 AM to 5 PM eastern daylight time and can be called toll-free by dialing (800)368-5855. You can have questions answered and be directed to sources in government and the private sector.

The "answer desk" can provide information on:

- Names and locations of financing sources
- Business programs available to the handicapped and minority groups
- Sources of management aid
- Lists of business sources and supplies
- Names of key contacts in state and federal government

Direct Mail/Direct Marketing

This may be an excellent area to consider allocating a portion of your advertising dollars. The newsletter "Data Base Marketing," reported that 83% of business-to-business marketers use direct mail to market their products or services. It has been estimated that direct mail accounts for approximately 7.5% of most business marketers' advertising budgets. The first step is proper planning. With proper planning, you should be able to avoid snags and maximize profitability.

Questions to ask yourself:

- Are you trying to build sales or profits?
- What are your long range goals?
- How does your product or service fit into the overall marketplace?
- When is it feasible/profitable to send mailings to your regular customers?
- How much should you spend?

The next step begins with obtaining a customer database. You can develop and maintain your own customer list or you can purchase mailing lists to find prospective customers. There are over 10,000 business lists available. The costs range between \$50 to \$150 per 1,000 names. Potential customers can be targeted by selecting names that fit specific geographic and demographic profiles.

For additional information on "Data Base Marketing" contact:

High Technology Associates, Inc.
5907 Penn Avenue
Suite 240
Pittsburgh, PA 15206

Questions You Can Not Ask a Job Applicant

As an employer, you want and need to obtain as much information as possible about a potential new employee. However, several questions should be avoided during the interview/hiring process. In conjunction, document all questions and responses on paper.

- **Are you married?** This is not a job related question and implies that private, outside factors could affect job performance. You may phrase a question to include, "Are there any circumstances which might affect possible overtime or travel?"
- **What is your age?** Avoid any and all questions pertaining to age. You can ask questions which pertain to specific skills, training, and experience.
- **What is your race or national origin?** The only way you can obtain this information is for confidential EEO (Equal Employment Opportunity) records. However, you must prove this information did not affect your hiring decision.
- **Are you disabled?** You can not prejudge the handicapped job seeker. However, you may ask the applicant if any worksite modifications would be necessary for them to perform the essential duties of the job.

Cost-Containment Efforts

Current—Not Resolved

There is no question that health care costs are rising. They are rising at a rate of 3% a year and it has been predicted that, if allowed to rise unchecked, they could consume 20% of the Gross National Product (GNP) by the year 2004. However, mandated cost containment measures, as is seen with generic (multi-source drugs) and therapeutic (single-source drugs) substitution applied indiscriminately and directed according to vague guidances may mean that for the first time in the history of the United States problems of an individual must be traded for the economic good of society.

Generic Substitution: It is delusional to automatically equate generic substitution with the achievement of cost containment. On average, generic drugs do cost less than do branded drugs, but for some drugs the difference in mean price is trivially small and, in some instances, the cost of the generic drugs is greater than that for a branded drug. Moreover, and more importantly, despite FDA assurances, uncertainties still remain, and, while major studies are lacking (who would fund them?), sufficient anecdotal evidence continues to mount and increase the uncertainties. Mandated, indiscriminate "switching" from one drug product to another (be it from a branded to a generic or generic to generic) does not take into account "critical" drugs, "critical" diseases and "critical" patients. Clearly, there is evidence that generic products are not always uniformly equivalent to branded drugs.

Therapeutic Substitution: This represents an effort to overcome costs of single-source drugs. It occurs in about 50% of hospitals and managed care systems, where, theoretically, a committee judges the appropriateness of substitution. Plans are under way to expand these efforts to the community, where the scientific/clinical input will be lacking and where governmental agencies, based on cost considerations alone, may mandate substitution. The potential for clinical inequivalence due to different chemical configuration of the drug molecules, due to change in dosage forms etc. is much greater following therapeutic substitution compared with generic substitution. Indeed, therapeutic substitution may alter therapeutic outcome, subject patients to substantial and unnecessary risk and increase cost instead of reducing it.

Lack of Cost-Containment Efforts

Making medications available for management of chronic diseases and for acute catastrophic events will only be a tentative approach to a more cost-effective use of drugs. One should consider other factors to make drug therapy optimal.

Redefinition of the "Ambulatory" Patient: "Ambulatory" has been defined as a patient not institutionalized. Implied in that definition has been the acceptance that the patient could present at a clinic for treatment. Care settings have changed. Home care is the fastest-growing segment of the health care market. For every patient residing in a nursing home, there are already four living in the community of comparable age and afflicted with equally serious medical problems. Thus, the patient may well be bed-bound or home-bound and could not be classified under the old classification of "ambulatory." "Not institutionalized" would be a much more descriptive and accurate classification.

Monitoring and Intervention—Non-Pharmacologic Approach: Therapy for chronic illness involves both pharmacologic and nonpharmacologic modalities. Approaching the broad scope of both of these requires the utilization of professional skills that include patient education, monitoring, counseling and follow-up. For hypertension, for example, this would involve dietary changes, cessation of smoking and alcohol intake, exercise, and still other approaches. Yet, in health care planning, and particularly in planning reimbursement, little or no consideration is given to the provision of these services, and, especially, for providing payment for these services.

Monitoring and Intervention—Compliance: In 1984, there were more than 125,000 deaths and several hundred thousand hospitalizations due to noncompliance with cardiovascular drugs alone (six of the 10 most frequently used drugs for patients 75 years old and over are cardiovascular drugs). In addition, approximately 20 million work days were lost representing an overall cost of \$1.5 billion to the national economy simply because prescribed cardiovascular drugs were not taken properly. HHS Assistant Secretary Robert Windom and FDA Commissioner Frank Young have correctly termed this "the other drug problem." They have stated that up to one-half of the 1.6 billion prescriptions each year are taken improperly. Pharmacists' (and other health care specialists') intervention and compliance efforts have proven that this problem can be alleviated to a large degree. Efforts, though, are limited due to lack of reimbursement policies.

Compliance Packing: The United States Pharmacopoeia has approved "Med-Pak." Studies have shown that over 20% of all admission of elderly to institutions are due to the patient's inability to handle medications. Medicaid has consistently refused to reimburse for packaging which will, among other benefits, enhance the patient's ability to remain at home by making it easier to self-administer medications.

Monitoring and Intervention—Therapeutic Outcome: The OTA has stated that drugs are the most cost-effective modality of long term care disease management, but that little is known about drug action when



A REVOLUTIONARY ORAL ANTIMICROBIAL WITH THE POWER OF PARENTERALS

- Highly active *in vitro* against a broad range of gram-positive and gram-negative pathogens, including methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa**
- For treatment of infections in the:
 - lower respiratory tract[†]
 - skin/skin structure[†]
 - urinary tract[†]
 - bones and joints[†]
- Convenient B.I.D. dosage – 250 mg, 500 mg and 750 mg tablets

**In vitro* activity does not necessarily imply a correlation with *in vivo* results.

[†]Due to susceptible strains of indicated pathogens. See indicated organisms in Brief Summary.

CIPRO® SHOULD NOT BE USED IN CHILDREN OR PREGNANT WOMEN.

A history of hypersensitivity to ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin.



Miles Inc.
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Please see adjacent page of this advertisement for Brief Summary of Prescribing Information.



**■ 500 mg B.I.D. for most infections;
750 mg B.I.D. for severe or complicated infections.**

BRIEF SUMMARY

CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Cipro® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Lower Respiratory Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, and *Streptococcus pneumoniae*.

Skin and Skin Structure Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* (penicillinase and nonpenicillinase-producing strains), *Staphylococcus epidermidis*, and *Streptococcus pyogenes*.

Bone and Joint Infections caused by *Enterobacter cloacae*, *Serratia marcescens*, and *Pseudomonas aeruginosa*.

Urinary Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter diversus*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, and *Streptococcus faecalis*.

Infectious Diarrhea caused by *Escherichia coli* (enterotoxigenic strains), *Campylobacter jejuni*, *Shigella flexneri*, and *Shigella sonnei** when antibacterial therapy is indicated.

*Efficacy for this organism in this organ system was studied in fewer than 10 infections.

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing infection and to determine their susceptibility to ciprofloxacin. Therapy with Cipro® may be initiated before results of these tests are known, once results become available appropriate therapy should be continued. As with other drugs, some strains of *Pseudomonas aeruginosa* may develop resistance fairly rapidly during treatment with ciprofloxacin. Culture and susceptibility testing performed periodically during therapy will provide information not only on the therapeutic effect of the antimicrobial agent but also on the possible emergence of bacterial resistance.

CONTRAINDICATIONS

A history of hypersensitivity to ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin.

WARNINGS

CIPROFLOXACIN SHOULD NOT BE USED IN CHILDREN OR PREGNANT WOMEN. The oral administration of ciprofloxacin caused lameness in immature dogs. Histopathological examination of the weight-bearing joints of these dogs revealed permanent lesions of the cartilage. Related drugs such as nalidixic acid, cinoxacin, and norfloxacin also produced erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION).

PRECAUTIONS

General As with other quinolones, ciprofloxacin may cause central nervous system (CNS) stimulation, which may lead to tremor, restlessness, lightheadedness, confusion, and very rarely to hallucinations or convulsive seizures. Therefore, ciprofloxacin should be used with caution in patients with known or suspected CNS disorders, such as severe cerebral arteriosclerosis or epilepsy, or other factors which predispose to seizures (SEE ADVERSE REACTIONS).

Crystals of ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine of laboratory animals. Crystalluria related to ciprofloxacin has been reported only rarely in man, because human urine is usually acidic. Patients receiving ciprofloxacin should be well hydrated, and alkalinity of the urine should be avoided. The recommended daily dose should not be exceeded. Alteration of the dosage regimen is necessary for patients with impairment of renal function (SEE DOSAGE AND ADMINISTRATION SECTION IN FULL PRESCRIBING INFORMATION).

Drug Interactions

Concurrent administration of ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions. If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate.

Antacids containing magnesium hydroxide or aluminum hydroxide may interfere with the absorption of ciprofloxacin, resulting in serum and urine levels lower than desired; concurrent administration of these agents with ciprofloxacin should be avoided.

Probencid interferes with the renal tubular secretion of ciprofloxacin and produces an increase in the level of ciprofloxacin in the serum. This should be considered if patients are receiving both drugs concomitantly.

As with other broad-spectrum antibiotics, prolonged use of ciprofloxacin may result in overgrowth of nonsusceptible organisms. Repeated evaluation of the patient's condition and microbial susceptibility testing is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Information for Patients

Patients should be advised that ciprofloxacin may be taken with or without meals. The preferred time of dosing is two hours after a meal. Patients should also be advised to drink fluids liberally and not take antacids containing magnesium or aluminum concomitantly or within two hours after dosing. Ciprofloxacin may cause dizziness or lightheadedness, therefore patients should know how they react to this drug before they operate an automobile or machinery or engage in activities requiring mental alertness or coordination.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin and the test results are listed below:

Salmonella/Microsome Test (Negative)

E. coli DNA Repair Assay (Negative)

Mouse Lymphoma Cell Forward Mutation Assay (Positive)

Chinese Hamster V₇₉ Cell HGPRT Test (Negative)

Syrian Hamster Embryo Cell Transformation Assay (Negative)

Saccharomyces cerevisiae Point Mutation Assay (Negative)

Saccharomyces cerevisiae Mitotic Crossover and Gene Conversion Assay (Negative)

Rat Hepatocyte DNA Repair Assay (Positive)

Thus, two of the eight tests were positive, but the following three *in vivo* test systems gave negative results:

Rat Hepatocyte DNA Repair Assay

Microtoxicity Test (Mice)

Dominant Lethal Test (Mice)

Long-term carcinogenicity studies in animals have not yet been completed.

Pregnancy – Pregnancy Category C

Reproduction studies have been performed in rats and mice at doses up to six times the usual daily human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ciprofloxacin. In rabbits, as with most antimicrobial agents, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion. No teratogenicity was observed at either dose. After intravenous administration, at doses up to 20 mg/kg, no maternal toxicity was produced, and no embryotoxicity or teratogenicity was observed. There are, however, no adequate and well-controlled studies in

CONVENIENT B.I.D. DOSAGE

Recommended dosage schedule

| Infection Site* | Severity of Infection | Dosage |
|----------------------|-----------------------|---------------|
| Respiratory Tract* | Mild/Moderate | 500 mg B.I.D. |
| Bone and Joint* | Severe/Complicated | 750 mg B.I.D. |
| Skin/Skin Structure* | Severe/Complicated | 500 mg B.I.D. |
| Urinary Tract* | Mild/Moderate | 250 mg B.I.D. |
| | Severe/Complicated | 500 mg B.I.D. |
| Infectious Diarrhea* | Mild/Moderate/Severe | 500 mg B.I.D. |

pregnant women. SINCE CIPROFLOXACIN, LIKE OTHER DRUGS IN ITS CLASS, CAUSES ARTHROPATHY IN IMMATURE ANIMALS, IT SHOULD NOT BE USED IN PREGNANT WOMEN (SEE WARNINGS).

Nursing Mothers

It is not known whether ciprofloxacin is excreted in human milk; however, it is known that ciprofloxacin is excreted in the milk of lactating rats and that other drugs of this class are excreted in human milk. Because of this, and because of the potential for serious adverse reactions from ciprofloxacin in nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Ciprofloxacin should not be used in children because it causes arthropathy in immature animals (SEE WARNINGS).

ADVERSE REACTIONS

Ciprofloxacin is generally well tolerated. During clinical investigation, 2,799 patients received 2,868 courses of the drug. Adverse events that were considered likely to be drug related occurred in 7.3% of courses, possibly related in 9.2%, and remotely related in 3.0%. Ciprofloxacin was discontinued because of an adverse event in 3.5% of courses, primarily involving the gastrointestinal system (1.5%), skin (0.6%), and central nervous system (0.4%).

The most frequently reported events, drug related or not, were nausea (5.2%), diarrhea (2.3%), vomiting (2.0%), abdominal pain/discomfort (1.7%), headache (1.2%), restlessness (1.1%), and rash (1.1%).

Additional events that occurred in less than 1% of ciprofloxacin courses are listed below. Those typical of quinolones are italicized.

GASTROINTESTINAL: (See above), painful oral mucosa, oral candidiasis, dysphagia, intestinal perforation, gastrointestinal bleeding.

CENTRAL NERVOUS SYSTEM: (See above), dizziness, lightheadedness, insomnia, nightmares, hallucinations, manic reaction, irritability, tremor, ataxia, convulsive seizures, lethargy, drowsiness, weakness, malaise, anorexia, phobia, depersonalization, depression, paresthesia

SKIN/HYPERSENSITIVITY: (See above), pruritus, urticaria, photosensitivity, flushing, fever, chills, angioedema, edema of the face, neck, lips, conjunctivae or hands, cutaneous candidiasis, hyperpigmentation, erythema nodosum.

SPECIAL SENSES: blurred vision, disturbed vision, (change in color perception, overbrightness of lights), decreased visual acuity, diplopia, eye pain, tinnitus, bad taste

MUSCULOSKELETAL: joint or back pain, joint stiffness, achesness, neck or chest pain, flare-up of gout

RENAL/UROGENITAL: interstitial nephritis, renal failure, polyuria, urinary retention, urethral bleeding, vaginitis, acidosis

CARDIOVASCULAR: palpitations, atrial flutter, ventricular ectopy, syncope, hypertension, angina pectoris, myocardial infarction, cardiopulmonary arrest, cerebral thrombosis

RESPIRATORY: epistaxis, laryngeal or pulmonary edema, hiccup, hemoptysis, dyspnea, bronchospasm, pulmonary embolism.

Most of these events were described as only mild or moderate in severity, abated soon after the drug was discontinued, and required no treatment.

In several instances, nausea, vomiting, tremor, restlessness, agitation, or palpitations were judged by investigators to be related to elevated plasma levels of theophylline possibly as a result of a drug interaction with ciprofloxacin.

Adverse Laboratory Changes: Changes in laboratory parameters listed as adverse events without regard to drug relationship:

Hepatic – Elevations of: ALT (SGPT) (1.9%), AST (SGOT) (1.7%), alkaline phosphatase (0.8%), LDH (0.4%), serum bilirubin (0.3%)

Hematologic – eosinophilia (0.6%), leukopenia (0.4%), decreased blood platelets (0.1%), elevated blood platelets (0.1%), pancytopenia (0.1%)

Renal – Elevations of: Serum creatinine (1.1%), BUN (0.9%)

CRYSTALLURIA, CYLINDURIA, AND HEMATURIA HAVE BEEN REPORTED

Other changes occurring in less than 0.1% of courses were: Elevation of serum gammaglutamyl transferase, elevation of serum amylase, reduction in blood glucose, elevated uric acid, decrease in hemoglobin, anemia, bleeding diathesis, increase in blood monocytes, and leukocytosis.

OVERDOSAGE

Information on overdosage in humans is not available. In the event of acute overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage. The patient should be carefully observed and given supportive treatment. Adequate hydration must be maintained. In the event of serious toxic reactions from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of ciprofloxacin from the body, particularly if renal function is compromised.

DOSAGE AND ADMINISTRATION

The usual adult dosage for patients with urinary tract infections is 250 mg every 12 hours. For patients with complicated infections caused by organisms not highly susceptible, 500 mg may be administered every 12 hours.

Respiratory tract infections, skin and skin structure infections, and bone and joint infections may be treated with 500 mg every 12 hours. For more severe or complicated infections, a dosage of 750 mg may be given every 12 hours.

The recommended dosage for infectious diarrhea is 500 mg every 12 hours.

In patients with renal impairment, some modification of dosage is recommended (SEE DOSAGE AND ADMINISTRATION SECTION IN FULL PRESCRIBING INFORMATION).

HOW SUPPLIED

Cipro® (ciprofloxacin HCl/Miles) is available as tablets of 250 mg, 500 mg, and 750 mg in bottles of 50, and in Unit-Dose packages of 100 (SEE FULL PRESCRIBING INFORMATION FOR COMPLETE INFORMATION).

* Due to susceptible strains of indicated pathogens. See indicated organisms in Brief Summary.

**For further information, contact the Miles Information Service:
1-800-642-4776. In VA, call collect: 703-391-7888.**

COMMITTED TO THERAPEUTIC EFFICIENCY



Miles Inc.
Pharmaceutical Division
400 Morgan Lane
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multiple drugs are used. The Royal College of Physicians has stated that one of the three major reasons for adverse drug reactions in the elderly is poor supervision of chronic care medications. Ten to 15% of admissions of elderly to hospitals are due to adverse drug reactions and, in its latest ADR report, the FDA has shown that people over 60 (17% of the population) accounted for one-third of all hospitalizations due to ADRs and nearly 50% of all death reports. On the other hand, in a large scale study, it was shown that nearly 68% of all drug interactions and ADRs could have been avoided and another 18% could probably have been avoided had current knowledge been applied. Pharmacists fulfill a medication review function in skilled nursing facilities (mandated by the Federal Government) but have not been assigned the monitoring function in the long-term care home sector. They should be.

Current Medicare Reimbursement for Outpatients

Note: The following information applies to persons eligible under Medicare Part B. Medicaid patients, of course, are reimbursed. Patients with Supplemental Insurance may recover some drug costs.

Current Medicare Drug Coverage: Drugs, per se, are *not* covered. However, there is a "back-door" approach. Under prosthetic device coverage, parenteral and enteral nutrition are reimbursed. A major problem exists. Use is approved only for patients unable to swallow and patients with malabsorption problems. Furthermore, treatment must be indefinite. Indefinite means that treatment must be given for more than 90 days. Patients who could benefit from a 60 day treatment are not eligible (cost could be \$15,000). A major problem exists with the timeliness of reimbursement. Some pharmacists literally have over \$100,000 outstanding, awaiting reimbursement.

Under durable medical equipment coverage, low volume infusion pumps are reimbursed and drugs used with these pumps are, therefore, also reimbursed. That would cover pain medication (morphine infusion), chelation therapy (iron overload) and insulin. Also covered would be chemotherapeutic agents (for colorectal cancer, for example), but *not* antibiotics.

Lack of Coverage: Antibiotics are not covered. Patients with life-threatening diseases such as osteomyelitis, endocarditis, and diverticulitis, in order to receive the necessary antibiotic infusion therapy, must be hospitalized. While antibiotics used in these instances may not be too expensive, there are cases where a patient may be penicillin-sensitive and more expensive drugs, such as vancomycin, must be used. A problem of the near future is AIDS. Elderly patients may have contacted AIDS via blood transfusions, and antibiotic treatment will be necessary.

The importance of antibiotics in the management of the elderly chronic care patient can be underscored with data from one mixed skilled/intermediate 97 bed facility. There was no influenza and no patient suffered from bed sores. Of the 97 patients, 22 were receiving

antibiotics for a wide range of problems. Drug cost (without dispensing or monitoring or laboratory fees) was over \$500 for the month reported.

Reimbursement for Prescription Drugs

Cost of Some Medications: Anti-ulcer drugs may cost \$50 to \$60/100, antibiotics \$90 to \$100/100, and anti-inflammatory drugs \$100 to \$120/100. Drugs on the horizon, such as Tissue Plasminogen Activators, to be given within 6 hrs after a myocardial infarction, may cost as much as \$1,000/treatment. Reimbursement of drugs alone may not be sufficient. A diabetic patient, for example, will need syringes and needles, urine testing equipment, and other items to be used in conjunction with medication to optimize medication effect. Lack of that would negate, in many instances, the effectiveness of management of the disease.

Reimbursement: It would be difficult, if not unfair, to single out any major drug category. It may well be possible to approve (prior approval) for reimbursement "standard" drugs, such as hydrochlorthiazide for the management of hypertension, for example. There may also be an upper limit. However, on documentation by the prescribing physician that a particular patient is unable to tolerate side effects of the "standard drug" and that a newer, likely more costly, agent would be necessary, the other agent could be reimbursed. There should also be a time limit, which will force re-evaluation of the need for any chronic care drug.

Given that there is likely to be a great deal of resistance to coverage of outpatient drugs under Medicare, one method which might prove politically palatable would be an indemnification program. Under this scheme, the patient would be responsible to the pharmacy for his own drug bills and then submit claims for reimbursement directly to Medicare. This would accomplish several objectives:

1. As mentioned before, it may be an acceptable first step.
2. It would also offer a great deal of flexibility. Drugs could be added a few at a time and could initially be placed on a "formulary" by class or diagnosis category.
3. Cost controls could be implemented such as deductible and/or coinsurance or copayment. The distinction:
 - a. Deductible (independent of other Medicare deductibles): The patient pays a first dollar amount per year for his drugs, say \$50.00. This drastically reduces program administrative costs and transfers at least the first \$50.00 from the program to the patient. (I believe HCFA will propose a \$500.00 dollar amount, which seems unreasonably high.)

Continued on page 20.

Patient Advice On Physician Dispensing

Patients Lose when Physicians Dispense

Advantages of Pharmacist Dispensing

1. Pharmacists reinforce doctors' drug therapy regimens by double checking drug strength, dosing schedule, and item prescribed. A patient medication record also reveals interactions and drug allergies.
2. Pharmacies stock a complete drug inventory of 1,000s of items. Most pharmacists target a 90%-95% instock availability of whatever drugs physicians prescribe.
3. Pharmacists must stock a full inventory of prescription and over-the-counter drugs to provide the best patient service possible. This guarantees that patient needs are met by giving physicians the broadest number of treatment alternatives.
4. Pharmacists detect and correct 1.2 severe life threatening interactions per day per pharmacy. Severe interactions could become commonplace if the pharmacist crosscheck were eliminated.
5. Pharmacist/patient counseling reinforces physicians directions and increases patient compliance.
6. Pharmacy locations and long operating hours allow for patient ease and convenience when prescriptions are first filled or refilled.
7. Patients are charged for their medications, there are no added/extra service charges for refills or new prescriptions.
8. Pharmacy is heavily regulated by state and federal laws. Consumers are protected because precise records, labeling, and storage requirements of drugs are mandated.
9. A complete medication profile of prescription and over-the-counter drugs are available from many pharmacies as are tax records.
10. Pharmacists can recognize counterfeit diverted drugs via subtle changes in the appearance of dosage forms.
11. Pharmacists can deliver or mail medications to homebound patients.
12. Patients often consult (for free) with pharmacists about routine ills. Physician dispensing jeopardizes this cost efficient service.

Disadvantages of Physician Dispensing

1. One person diagnosing, prescribing, and dispensing drugs is monopolistic. It concentrates tremendous drug product selection authority in one individual, and it decreases competition which leads to price gouging.
2. Physicians who dispense, profit from the medications they select, these drugs may not be what the patient needs—there is constant temptation to overprescribe.
3. Companies that supply dispensing doctors limit the scope of physicians' treatment alternatives thereby depriving patients of the medication they actually need. Physicians dispense what is stocked rather than the drug of choice for a specific condition.
4. When physicians dispense, there are no systems of checks and balances. If a mistake or interaction occurs it will not be detected.
5. Probable dispensing by nonprofessionals (receptionist or appointment/secretary) without direct supervision eliminates meaningful patient communication.
6. Limited availability of dispensing physicians means that refills will be processed only during office hours.
7. Dispensing physicians may charge for an office visit when refills are needed.
8. Dispensing physicians operate unregulated. There are no rules specifying proper storage, labeling or patient records.
9. Doctors don't have a complete medication profile because many patients visit more than one physician (specialist). Patients also self medicate and these drugs often aren't in a doctor's patient profile.
10. Dispensing physicians (or their surrogates) are less likely to recognize counterfeit diverted drugs.
11. It is difficult or impossible for handicapped or older geriatric patients to obtain their medication needs from dispensing physicians.
12. Loss of neighborhood pharmacies removes a valuable health resource from the community. It also cuts into the local tax base.

If your physician tries to dispense a product to you instead of providing you a prescription—just say no. And remember to ask for a copy of the prescription, you've paid for it.

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2. ARE YOUR PRESCRIPTION CUSTOMERS BUYING THEIR HBA'S FROM YOUR COMPETITION? (CHAINS, MASS MERCHANDISERS, GROCERY STORES)
3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AffECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

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THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

LAMBDA KAPPA SIGMA sorority is planning its 75th Anniversary, August 2-6, 1988 at the Copley Plaza Hotel in Boston. All LKS sisters are encouraged to come and celebrate the future of LKS and women in pharmacy. For details, contact Mary Greer at Lambda Kappa Sigma, P.O. Box 981, Claremont, OK 74018.

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calendar



- June 5 (Sun.)—CECC—Substance Abuse Among Pharmacy Staff
- June 5-9—ASHP Annual Meeting—San Francisco
- June 12 (Sun.)—AZO Installation Dinner Meeting
- June 19-23—MPhA CONVENTION—SHERATON OCEAN CITY—RESERVE YOUR SPOT IN THE SUN
- Oct. 21 (Fri.)—MSHP Annual Seminar—Sheraton Ocean City, Md.

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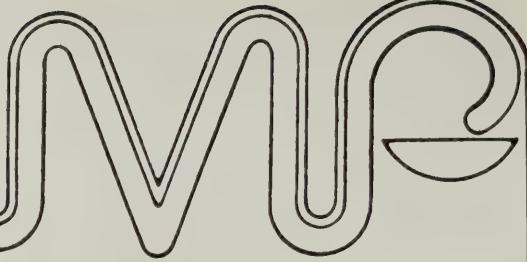
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*Elwin Alpern
1988-1989 MPhA President*

THE MARYLAND PHARMACIST

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Commentary

As we all are aware, private practice physicians are finding themselves squeezed from all sides. Cost containment pressures are stripping doctors of incomes that they have been used to receiving. The doctor glut of too many for too few is worsening. The proliferation of managed care settings and HMOs are driving up the competition for the already shrinking patient base. Fewer physicians are looking to private practice as they complete their residencies than ever before.

The climate for for-profit physician dispensing in Maryland is rapidly growing worse. Despite our efforts to enact legislation regulating this practice, no regulations have been published or put into action. It has come to our attention that several drug repackagers are taking advantage of this climate to launch major campaigns to recruit physicians to dispense from their "boxes."

You know the repackager's sales pitch already. "It's convenient for the patient," they cry. "Make sure your patients receive the medicine *you* prescribe." they add. "And, it's cheaper for them too, and you'll make the big profits just like the pharmacists do," they wheedle. No wonder that many physicians succumb to their ploys.

Your association has formed a committee to meet with the presidents of the local medical societies and discuss this situation. This committee brings together chains, independents, hospitals, and the school. So far, the medical societies have been unable to find a "convenient" time to meet with us. We expect to succeed in protecting Maryland pharmacy from this public health hazard.



Elwin Alpern, P.D.
President

President's Tip

In order to participate in the upcoming federal Medicare Outpatient Prescription Program, a pharmacist will have to monitor interactions and counsel patients. This can only be done efficiently with a computer. Although you will be provided with a terminal to keep track of deductibles and copayments, now is the time to consider full pharmacy automation.

Continuing Education

New Drug Update for 1988

by Thomas A. Gossel, R.Ph., Ph.D.

Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to identify new drugs approved by FDA and/or marketed in 1987 and 1988.

Objectives

At the conclusion of this lesson, the participant will be able to:

1. exhibit knowledge of the drugs by pharmacologic and therapeutic classification;



Gossel

Wuest

2. choose the indications, mechanism of action, pharmacokinetic properties, and benefits and limitations;
3. identify adverse effects and drug interactions associated with the drugs; and
4. demonstrate an ability to counsel patients on these new drugs.

Recently approved and/or marketed new chemical drug entities (Table 1) comprise, for the most part, two main categories: cardiovascular agents and anti-infectives. The other new drugs represent a variety of pharmacologic categories. Of special interest is the number of agents that are derived from recombinant DNA technology. Four such drugs were approved during the past year.

This article provides an overview of the cardiovascular and anti-inflammatory new drugs that were approved and/or marketed during 1987 and 1988. The remaining drugs will be discussed in Part II of this two-part series.

Activase (alteplase, recombinant)

Also known as TPA and t-PA, alteplase, recombinant is the generic name for tissue plasminogen activator. The "recombinant" term is used as a modifier because the drug is produced by bacterial colonies via recombinant DNA technology rather

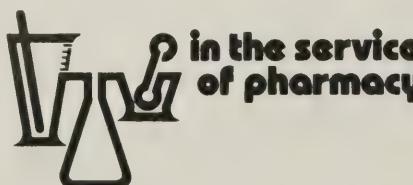
than chemical synthesis. Activase is a thrombolytic agent for use in persons with a recent acute myocardial infarction (MI).

Tissue plasminogen activator is an endogenous protein that occurs naturally in humans, and is found throughout the vasculature system. Following formation of a fibrin clot within the vasculature, TPA activates plasminogen by converting it to its active form, plasmin. Plasmin is an enzyme that lyses fibrin to help maintain the fluidity of blood.

Activase is administered intravenously, as quickly after a myocardial infarction as possible. It has produced coronary recanalization in 60 percent or more patients within 90 minutes. These responses are comparable to or greater than results with streptokinase and urokinase, the previously available thrombolytic agents.

Primary concerns of therapy of acute MI are reinfarction, arrhythmias, and bleeding. The latter is reportedly less common and less severe with TPA than with other thrombolytic agents, since it is more specific for fibrin. It must bind to fibrin to exert its action; thus, it increases the plasmin level mainly at the site of the clot, rather than throughout the systemic circulation. In clinical trials, investigators have reported that after reperfusion, arrhythmias and reinfarction have been less severe than with other thrombolytic agents.

More study will be required before the true value of this drug can be determined. Some studies show that overall TPA is not superior to other thrombolytic agents. The original double-blind studies were discontinued because the drug produced such significantly better results than placebo, that researchers felt it was unethical to withhold the drug from the patients in the placebo group.



This continuing education for Pharmacy article is provided through a grant from

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Table 1**New Drugs Approved and/or Marketed in 1987 and 1988**

| Trade Name | Generic Name | Manufacturer | Use |
|-------------|--|----------------------------|------------------------------|
| Aclovate | Alclometasone | Glaxo | Topical steroid |
| Activase | Alteplase, recombinant | Genentech | Antithrombotic |
| Alfenta | Alfentanil | Janssen | Anesthetic adjunct |
| Atrovent | Ipratropium | Boehringer Ingelheim | Bronchodilator |
| Azactam | Aztreonam | Squibb | Antibiotic |
| Bactroban | Mupirocin | Beecham | Antibiotic |
| Brevibloc | Esmolol | DuPont | Beta-adrenergic blocker |
| Cefmax | Cefmenoxime | Abbott | Antibiotic |
| Cipro | Ciprofloxacin | Miles | Anti-infective |
| Corotrope | Milrinone | Sterling | Inotropic |
| Cyklokapron | Tranexamic acid | KabiVitrum | Hemostatic |
| Deursil | Ursodiol | Gipharmex S.p.A. | Gallstone dissolver |
| Elocon | Mometasone | Schering | Topical steroid |
| Enkaid | Encainide | Bristol | Antiarrhythmic |
| Humatropae | Somatropin | Lilly | Growth hormone |
| Hytrin | Terazosin | Abbott, Burroughs Wellcome | Antihypertensive |
| Iopidine | Aplonidine | Alcon | Ophthalmic |
| Lamprene | Clofazimine | Geigy | Anti-infective |
| Levatol | Penbutolol | Lilly | Beta-adrenergic blocker |
| Metrodin | Urofollitropin | Serono | Gonadotropin |
| Mevacor | Lovastatin | Merck, Sharp & Dohme | Anticholesterolemic |
| Monoclate | Antihemophilic factor VIII:C | Armour | Clotting factor |
| Noroxin | Norfloxacin | Merck, Sharp & Dohme | Anti-infective |
| Novantrone | Mitoxantrone | Lederle | Antineoplastic |
| Ocufen | Flurbiprofen | Allergan | NSAID |
| Prinivil | Lisinopril | Merck, Sharp & Dohme | Antihypertensive |
| ProHIBIT | Haemophilus b conjugate vaccine | Connaught | Immunological |
| Prolastin | Alpha ₁ -Proteinase inhibitor | Miles | Emphysema |
| Prozac | Fluoxetine | Lilly | Antidepressant |
| Retrovir | Zidovudine | Burroughs Wellcome | Antiviral |
| Rimadyl | Carprofen | Roche | NSAID |
| Rowasa | Mesalamine | Reid-Rowell | Anti-inflammatory |
| Tenex | Guanfacine | Robins | Antihypertensive |
| Terazol-7 | Terconazole | Ortho | Antifungal |
| Ucephane | Sodium benzoate/Sodium phenylacetate | Kendall McGaw | Prevent/treat hyperammonemia |
| Unasyn | Ampicillin/Sulbactam | Roerig | Antibiotic |
| Zestril | Lisinopril | I.C.I. | Antihypertensive |

Activase has already made an impact in the marketplace. During the first month of introduction, sales averaged \$1.5 million per day.

Brevibloc (esmolol)

A parenterally administered, cardioselective beta-adrenergic blocker, Brevibloc has an elimination half-

life of approximately 9 minutes. It is indicated for emergency treatment of supraventricular tachycardia or other pathologic conditions that warrant short-term control of irregular rapid ventricular rate. Beta-adrenergic blockers are valuable because they reduce sympathetic stimulation to heart muscle and reduce oxygen demand, actions which help

prevent myocardial tissue necrosis. Brevibloc is administered to stabilize the patient until more specific or appropriate therapy can be instituted.

Corotrope (milrinone)

Corotrope is an inotropic agent that is chemically related to previously available amrinone (Inocor) and approximately 20 times more potent. It is also safer in that drug-induced arrhythmias and thrombocytopenia caused by amrinone have not been seen with milrinone.

Traditionally, digitalis, and more recently amrinone, have been used for short-term emergency intravenous treatment of refractive CHF. Both digitalis and amrinone are potentially toxic. It is anticipated that milrinone will cut into the amrinone market.

The new drug, as with its predecessor, is believed to work by inhibiting phosphodiesterase. This in turn increases intracellular c-AMP which then enhances calcium utilization. It may also exert other direct effects on transmembrane calcium movement. The net result is an increase in the strength and force of heart muscle contractions, making these drugs inotropic. Its manufacturer hopes to eventually market an oral dosage form which could possibly cut into the digoxin market for treating chronic congestive heart failure.

Cyklokapron (tranexamic acid)

This new drug is indicated for short-term use of 2 to 8 days in hemophilia patients during and following tooth extraction. A competitive inhibitor of plasminogen and non-competitive inhibitor of plasmin, the drug permits fibrin clots to form. By inhibiting formation and action of plasmin, Cyklokapron prevents excessive breakdown of fibrin, thereby enhancing clot formation, and preventing hemorrhage.

Enkaid (encainide)

Since Enkaid blocks the movement of sodium across cell membranes in Purkinje fibers and the myocardium, it is classed pharmacologically as a "1C" antiarrhythmic, joining flecainide (Tambocor). It slows depo-

larization but has little effect on the duration of the action potential or upon repolarization. Drug action appears to be greater on cells in ischemic, rather than normal, areas.

Enkaid is indicated for treatment of life-threatening ventricular arrhythmias. Clinical trials showed that it abolishes nonsustained ventricular tachycardia in 70 percent of patients, and suppresses premature ventricular contraction by 90 percent in over 60 percent of patients studied.

As with other antiarrhythmics, Enkaid can also cause arrhythmias so its use must be weighed against the risks associated with therapy. Ten percent of patients have experienced aggravated ventricular arrhythmias. Dizziness, blurred or abnormal vision, and headache are the most commonly reported adverse effects. No serious drug interactions have yet been reported, but potentiation of other antiarrhythmics can be anticipated.

Hytrin (terazosin)

Hytrin is classed pharmacologically as an alpha₁-adrenergic blocker, joining prazosin (Minipress) in that classification. However, it is the first of its class to be effective with once-daily dosing.

Like prazosin and other alpha₁-adrenergic blockers, terazosin may cause marked hypotension with the first dose, resulting in lightheadedness and fainting (syncope), usually occurring within 90 minutes of dosing. A similar effect occurs if chronic therapy is interrupted for more than a few doses and then reinstated.

To decrease the chance of syncope or postural hypotension when initiating therapy, the first dose (1 mg) should be taken at bedtime. Dosage can be adjusted upward from 1 mg if needed.

Other adverse effects that are most often reported include palpitations, dizziness, weakness and nausea.

There are two unusual phenomena in the marketing of Hytrin. First, all dosage strengths are priced the same. It is felt that this one-price policy will enhance compliance by patients who are started on the lower strength tablets and then switched to higher strength tablets. The second is that terazosin will be co-marketed by two

manufacturers under the same trademark.

Levatol (penbutolol)

This nonselective beta-adrenergic blocker has a long half-life which permits once-daily dosing. Approved in December 1987, its sponsor has noted that it may not proceed with marketing.

Mevacor (lovastatin)

Mevacor, a serum cholesterol lowering agent, works by inhibiting the enzyme HMG-CoA reductase. This is the rate-limiting step that regulates cholesterol synthesis.

Mevacor is indicated as an adjunct to diet in lowering elevated levels of low density lipoprotein (LDL) cholesterol and total cholesterol in patients with Types IIa and IIb (Primary) hypercholesterolemia. It also elevates levels of high density lipoprotein (HDL) cholesterol. It is recommended that patients first be assessed for response to dietary control alone, and then dosed with Mevacor if non-drug measures do not control the disease. The drug should bring about marked clinical response within 2 weeks of initiating therapy, with maximum therapeutic response in 4 to 6 weeks.

High LDL cholesterol, and reduced HDL cholesterol levels are important risk factors for coronary heart disease. Briefly, LDL transports cholesterol to tissues such as arterial walls where it may accumulate to form plaque. HDL transports cholesterol back to the liver where it is transformed into bile acids, or secreted into the gallbladder for excretion.

Mevacor is generally well tolerated and causes few adverse effects. Most common subjective responses are gastrointestinal (5 percent), skin rash/pruritus (5 percent), and headache (9 percent). Less than 1 percent of patients in clinical trials were removed due to adverse effects.

The dose range is 20 to 80 mg/day. Recommended titration is 20 mg daily for several weeks, advancing in increments of 20 mg daily up to 80 mg. It is felt that if patients do not respond to 80 mg daily, the drug will not be effective for them. Optimally, Mevacor tablets should be taken with the evening meal since chole-

sterol synthesis is most active between midnight and 3:00 a.m. Patients should be strongly advised to comply with both their dosage regimen and the dietary restrictions provided by their physicians because the drug is an adjunct to treatment, not a cure.

Monoclate (antihemophilic factor VIII)

A product of recombinant DNA technology, Monoclate restores the blood clotting factor VIII. Such deficiency is characteristic of patients with hemophilia A. The drug was developed because the only source of this factor for hemophiliacs was human blood donors. The fear and reality of the presence of HIV and hepatitis virus in those earlier, less purified products made the development of Monoclate a worthwhile endeavor.

Prinivil/Zestril (lisinopril)

Lisinopril is the first of several "second generation" angiotensin converting enzyme (ACE) inhibitors to be approved for marketing in the U.S. While pharmacologically similar to both enalapril (Vasotec) and captopril (Capoten), its primary advantage is its longer half-life, hence, once-daily dosing.

ACE inhibitors act upon the enzyme which converts angiotensin I to angiotensin II. Angiotensin II normally causes physiological responses such as direct and indirect vasoconstriction, and retention of aldosterone, which in turn raise the blood pressure. Reducing its formation by suppressing ACE leads to a lowering of the pressure. Studies have shown that 5 to 10 mg/day of lisinopril is effective in most patients with mild to moderate essential hypertension.

ACE inhibitors affect aldosterone action, which in turn can increase potassium retention. The potentially most significant drug interaction involving lisinopril may be the possibility of hyperkalemia if potassium supplements or potassium-retaining diuretics are taken concurrently.

Lisinopril has not yet been associated with hematologic, cardiovascular, or CNS toxicity as has its structural analogue, enalapril. The bioavailability of lisinopril is unaf-

fected by co-administration of food.

It has not yet been compared pharmacologically or therapeutically to the other ACE inhibitors in controlled clinical trials. The ultimate place in therapy for lisinopril remains to be determined, but the current trend toward once a day dosing points to significant usage.

Tenex (guanfacine)

Tenex is a centrally acting alpha₂-adrenergic stimulant, joining clonidine (Catapres) and guanabenz (Wytensin) in this classification. Such pharmacologic action reduces sympathetic stimulation from the vaso-motor center in the brain to the heart and blood vessels, resulting in decreased arterial vasoconstriction and lower peripheral resistance. Blood pressure and heart rate are reduced, but cardiac output is not significantly altered. Tenex is indicated for management of mild to moderate essential hypertension.

Adverse effects are qualitatively the same as for other central alpha₂-adrenergic stimulants. The most common reactions include dry mouth (40 percent), constipation (16 percent), fatigue (12 percent), somnolence (10 percent), and dizziness (6 percent). These reactions are mild and tend to disappear on continued use. The claimed advantage of Tenex over earlier available products include a lower incidence of CNS side effects, and once-daily dosing. There is also less rebound hypertension if therapy is abruptly discontinued.

Nonetheless, Tenex can cause rebound hypertension on abrupt withdrawal of medication once the patient is stabilized. If this occurs, it will appear within 2 to 3 days (versus 12 to 24 hours with clonidine) due to the agent's longer biological half-life.

The drug is taken once a day, preferably at bedtime. It is recommended that patients be stabilized on a diuretic before the drug is initiated to reduce their overall fluid volume.

Anti-Inflammatory Agents

Aclovate (alclometasone) Elocin (mometasone)

As with previously available top-

ical corticosteroids, these two products are indicated for itching and inflammation associated with corticosteroid-responsive skin disorders. It is of some interest that despite the introduction of dozens of topical steroids, and their long and wide-spread use, their exact mechanism of action has not been determined. These agents appear to act similarly to the others by inhibiting the body's immune system and reducing its inflammation component.

Both drugs have a low potential for adverse reactions when used as directed. Aclovate cream or ointment should be applied two or three times a day; Elocin cream is applied once daily. Both products should be applied in a thin layer, and not covered with an occlusive dressing unless the physician specifically directs it.

Ocufen (flurbiprofen)

This NSAID possesses analgesic, antipyretic and anti-inflammatory activity. Like other NSAIDs, it is believed to inhibit prostaglandin synthesis.

Ocufen is marketed as an ophthalmic solution indicated for prevention of miosis during surgery. It is instilled into the eye prior to surgery. Prostaglandins have been shown to mediate intraocular inflammation and induce miosis. Hence, prostaglandin inhibition reduces inflammation and prevents excessive miosis.

Look for fluriprofen to also enter the marketplace in an oral dosage form. Its pharmacology is similar to that of other oral NSAIDs.

Rimadyl (carprofen)

Possibly the most important point about this drug is that it is the first new systemic NSAID, of a backlog of a half dozen or so, to be approved in over two years. Rimadyl has a similar therapeutic profile to other NSAIDs already available. The main advantage claimed is that it has lower gastrointestinal (GI) toxicity. Animal studies show it is at least 16 times less ulcerogenic than indomethacin, which, was the reason it was developed — to replace indomethacin. There are no studies that compare it with other members of this chemical class.

Rimadyl can be taken twice a day

by most patients. The usual dose for analgesia is 150 mg twice daily, but doses as high as 600 mg twice daily have been employed when utilized for inflammatory conditions.

Like other NSAIDs, it inhibits prostaglandin synthesis. However, its inhibition appears to be relatively selective, with minimal activity on prostaglandin E₂ (a cytoprotective prostaglandin). It is speculated that this selective action is responsible for its lower GI toxicity.

Rowasa (mesalamine)

As background, sulfasalazine has been the drug of choice for ulcerative colitis and distal inflammatory bowel disease for about 4 decades. Sulfasalazine is a combination of 2 chemical moieties, sulfapyridine and 5-aminosalicylic acid (5ASA), linked by an azo bond. Following ingestion, about one-third of a dose is absorbed. The remainder passes on to the colon. Colonic enzymes split the unabsorbed drug into its component molecules, sulfapyridine and its active group, 5ASA. Absorbed drug is also split, then further metabolized and excreted. Toxicity (nausea, vomiting, headache, malaise, hemolysis, hypersensitivity) is a problem with sulfasalazine and is directly proportional to blood levels of sulfapyridine.

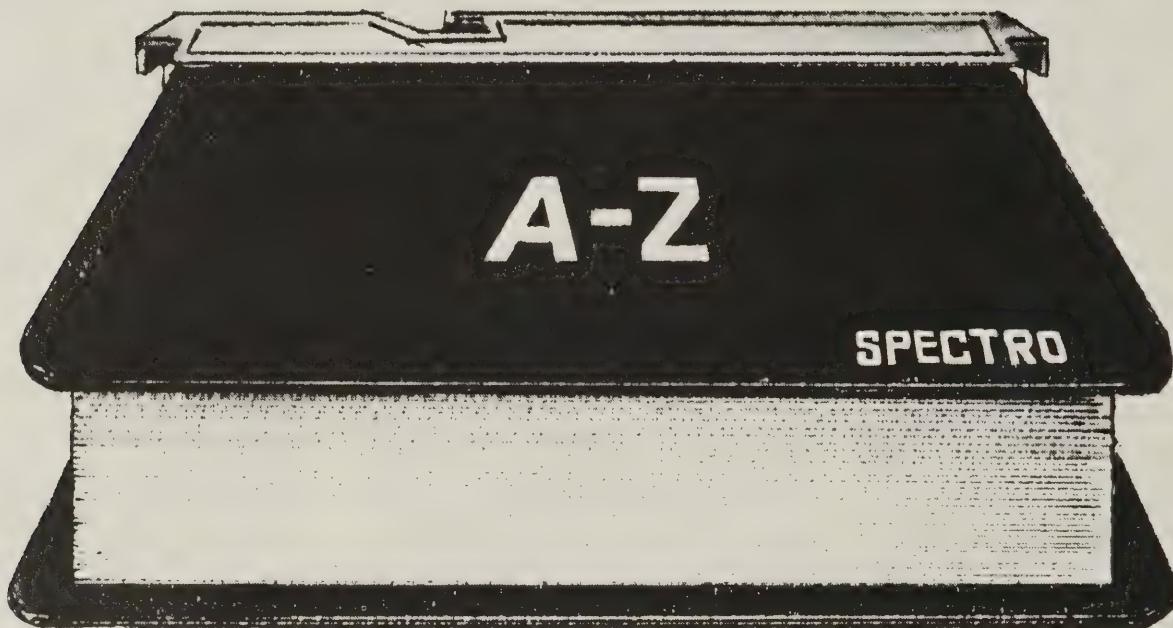
Rowasa is a stable form of 5ASA. Since it does not contain a sulfonamide group (i.e., sulfapyridine), it causes fewer side effects. On the other hand, the therapeutic activity of sulfasalazine results from the 5ASA component, so mesalamine provides the benefits with less risk.

The mechanism of anti-inflammatory action of 5ASA is postulated to result from prostaglandin inhibition (salicylates are members of the NSAID group). An alternate hypothesis is that 5ASA inhibits leukotriene production by neutrophils.

Studies have shown that 5ASA enemas are more effective than hydrocortisone enemas in treatment of ulcerative colitis. Initially available as a disposable enema, an oral tablet and rectal suppository dosage form may be available in the future.

In the next lesson of the series, the nearly two dozen other drugs that were approved and/or marketed in 1987 and 1988 will be reviewed.

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SPEAKER OF THE HOUSE REPORT

Chairperson—*Brian Sanderoff*

As the speaker of the House of Delegates for 1987-88 it has been my honor and my privilege to serve and represent you. It has been one busy year.

One of the resolutions from last year's meeting mandated that the Constitution and Bylaws be revised and presented for vote at this year's meeting. After exhausting work by Chairman Cogan and his committee, the preliminary copy was presented to and approved by this House at the Mid-Year Meeting and the final copy will be voted on at the Annual Convention this week. Every member of the committee was a delegate to this House and thus our interests were well protected.

In January we learned that our Executive Director and long time friend David Banta was to leave our Association for bigger and better things. As Speaker, I felt it imperative that the House have a voice in the selection of the new Executive Director. I was a member of the Search Committee, partaking in interview and the final selection of Executive Director that will take us to the next level of Association Existence.

At the Mid-Year Meeting in Annapolis the House approved the slate of officers for election in April. We also approved the slate of the Board of Pharmacy Commissioners that we later presented to Governor Schaeffer.

In March, I was a delegate to the Annual meeting of the APhA representing our Association. There were several issues that APhA took stands that I think we will want to discuss. Several of our resolutions will address these issues.

In closing, I would like to thank all of you for your trust and support throughout the year. It is only with your help that anything gets accomplished for this House of Delegates and our Association. I look forward to serving as Vice-President next year!

TRAVEL AND CONVENTION REPORT

Chairman—*Elwin Alpern*

Our trip to Curacao, January 1988, was well attended. We all shared breakfast each morning and continuing education daily. We received 8 hours of CE credit which was done at a leisurely pace, and we had the advantage of daily informal discussion periods. Our topic was most timely: "Drug Abuse—What, Who, How and Why and Strategies for Prevention and Treatment." Eli Lilly and Company put the booklet together and our thanks go to them. Our Association realized a profit of \$1,750.00 on this trip.

Our 1987 convention at the Sheraton attracted 38 paid exhibitors with a gross of \$11,650.00. There were contributions of \$5,440.00 and a registration of \$13,999.51. The net profit was \$8,951.11. This was less than last year due to a decrease in the number of registrants, which cost us \$2,698.89 in revenues. Our expenses to the Sheraton were up which forced us to raise fees to exhibitors in order to build our revenues back to the success of last year's convention. Our Association for the year realized \$10,701.11 in revenues. (1987-1988)

In January 18-25, 1989, we will travel to Aruba. Our price is very good and we will again offer CE for credits. We will advertise here at the convention as well as in three other mailings. Space is limited to 80 persons, so do NOT delay.

I would like to thank Beverly Litsinger, David Miller, and Jerry Freedenburg for their help. Thank you all for your continued support.



Pharmacists from all areas of practice crowded the continuing education and business sessions.

LEGISLATIVE COMMITTEE REPORT

Chairman—Nathaniel Futerl

The Maryland Pharmacists Association sponsored a legislative breakfast in Annapolis. It was well attended by members from around the state, as well as by many Senators and Delegates. The highlight was the arrival of Governor William Donald Schaefer and Lieutenant Governor Melvin Steinberg. Both distinguished guests addressed our group and urged us to stay active and involved in the legislative process.

I wish to thank the membership for their generous responses to the special legislative fund solicitation needed to hire a lobbyist. Robin Shaivitz was hired to lobby for the Maryland Pharmacists Association and she did an outstanding job monitoring the legislation and representing the Association in Annapolis. I hope that everyone will respond again this year to the lobbying fund so that we can continue our success in Annapolis.

The Association worked in close cooperation with a number of coalitions of health professional groups to influence legislation that encouraged quality of health care delivery. We were instrumental in seeing some of our initiatives in that area pass.

One of the problems dealt with during the legislative session was a plan to increase the amount of co-payment for prescriptions for Medicaid and pharmacy assistance recipients. The Administration proposed in the budget to increase federal Medicaid from \$0.50 to \$2.00 for State-only Medicaid, from \$0.00 to \$2.00 for the rest, and (Pharmacy Assistance) from (\$1.00 to \$5.00). In addition, the Administration proposed requiring all General Public Assistance (GPA) recipients living in Baltimore City and parts of Anne Arundel County to use a health maintenance organization as part of a managed care program. We recognized that the costs of the Medical Care program were sky rocketing, but do not believe that the budget problems should fall on Maryland pharmacists and the poor. We met with the Deputy Secretary for DHMH, Nelson Sabatini. He was very open to our suggestions of ways to reduce costs. We testified in opposition to SB 375, the Maryland Pharmacy Assistance Program increases, and in opposition to that portion of DHMH's budget dealing with the increases in the Medicaid co-payments and managed care. We were successful on both counts: 1) SB372 was defeated in the Senate Finance Committee 2) Budget narrative was added to the fiscal year 1989 budget insisting that DHMH develop other alternatives for saving money.

The Maryland pharmacists were eager to see legislation pass this year that would have prevented third party payers from discriminating against pharmacy walk-in business as opposed to mail order pharmacy



Legislative Committee Chairman and MPhA President Elect Nat Futerl brings attendees up-to-speed on the issues.

plans. HB 435, sponsored by Delegate Casper Taylor, and its companion, SB 377, sponsored by Senators Michael Wagner and Edward Kasemeyer, were designed to prohibit an insurer or HMO from waiving a co-pay for mail order business and insisting on a co-pay for the beneficiary or member who chose to get the prescription filled at a local pharmacy. The issue was one of fairness and freedom of choice. Unfortunately, the extensive opposition did not feel the same way as these bills were opposed by Blue Cross/Blue Shield, independent health insurers, the HMO Association, the Maryland Chamber of Commerce and organized labor. Although there was the strong possibility that HB 435 could have passed the House Economic Matters Committee and perhaps the floor of the House, it was believed that it would be doomed to be defeated this year in the Senate. It was decided that our best strategy was to ask the Economic Matters Committee to study it during the summer and make some recommendations.

If the Association is to be successful in this issue, we must do the following: develop a proposal for the Economic Matters Committee, monitor and participate in the summer study, contact members of the Economic Matters Committee and the Senate Finance Committee to let them know we need their support, develop a coalition of support from allied groups (Office on Aging, Seniors United, labor, other health professionals).

I can't stress enough the importance of combined efforts of the health coalition, the membership, and our lobbyists, to bring about success in our legislative efforts. With proper planning and participation among our members, MPhA will continue to be successful with important pharmacy issues.

It has been my pleasure to serve as your Legislative Chairman. I would like to thank all the members who volunteered their efforts over the year. Additionally, I would like to thank and compliment Robin Shaivitz for a job well done. I would also like to express my personal appreciation to each of the MPhA staff for their support.

CONSTITUTION AND BYLAWS REPORT

Co-Chairmen: Philip H. Cogan and William J. Skinner

The Constitution and Bylaws Committee met several times during the summer of 1987 to review the existing Constitution and Bylaws and to propose revisions that would bring it up to date.

Documentation was sketchy, but available information indicated that it had been at least 30 years since major changes in the Constitution and Bylaws were made. From time to time, there have been amendments, but the Association's Constitution and Bylaws were awkward, piecemeal and sorely out of date. The Committee reviewed recently developed bylaws from other state pharmacy associations and consulting several references on the subject. Its conclusion was that it would be better to start from scratch in developing new bylaws as opposed to conducting delicate surgery in a patchwork fashion on the old ones.

The major change was to eliminate references alluding to "constitution," since the Association's Articles of Incorporation, filed with the State, are considered the constitution. The principal task facing the Committee therefore, was to develop bylaws that were firm enough to keep the Association on course for a long time without being so inflexible that they could not accommodate a rapidly changing society.

The existing Constitution and Bylaws consisted of four separate documents with a rigid structure for the Association as well as detailed provisions lodged within for such diverse organizations as the "Joint Students' Branch of the American Pharmaceutical Association and Maryland Pharmacists Association" and the Ladies' Auxiliary. The Students' Branch has not existed as such for approximately 30 years.

In the fall of 1987, the Board of Trustees commented on the proposed bylaws and approved the draft that was published in the January 1988 issue of "The Maryland Pharmacist." The House of Delegates considered the proposed bylaws for the first time in February 1988 and recommended a few technical changes which were made.

It is now up to the House of Delegates to accept or reject the effort upon their second consideration at the 1988 convention.

The House of Delegates adopted the new Constitution and Bylaws at the Second General business Session, June 22, 1988. For a final copy, please write the MPhA offices.

NEWSLETTER COMMITTEE REPORT

Chairman—Melvin Rubin

The Newsletter was distributed every month with a combined summer edition in July/August. The format was changed slightly in April to make it more easily readable. Emphasis is still on information and news about members and other goings-on, especially with any legislative commotion. Unfortunately, the newsletter has a decided Baltimore area flavor since very little information is sent to the MPhA office from other areas of the state. An exception is the Frederick County local association which sends monthly newsletters to the MPhA and we pass it on to the membership.

As every year, we solicit local organizations to forward information for publication. Suggestions for articles in the Convention issue are solicited also. With your input, the Newsletter can be made better.



MSHP President Paul Jeffrey greets MPhA members on behalf of the hospital pharmacists.

PEER REVIEW COMMITTEE REPORT

Chairman: Beverly Yachmetz

Over the past year, only one complaint was received by the Committee. The complaint was vague and needed further discussion with the consumer. However, I made several attempts to contact the person leaving detailed messages on his answering tape but he never responded. After talking to Dave Banta, it was decided the person was not interested in pursuing the matter.



SCHOLARSHIP COMMITTEE REPORT

Chairman—Brian Sanderoff

The Scholarship Committee met in April, and made the selection for this year's scholarship winners. It was a difficult decision with the many applicants.

PEP scholarships are awarded to students who show a need for financial assistance during the summer months while they do externships. The awards are in the amount of \$300.00 each. This year's recipients were:

Michele Foster, 3rd professional year
Rebecca A. Sowers, 3rd professional year

The Harry D. Kaufman Award is presented to students who have demonstrated outstanding dedication and devotion to community service. The award is in the amount of \$100.00. This year's selection for the Kaufman scholarship was:

Mari Kim, 5th professional year

EMPLOYER/EMPLOYEE RELATIONS COMMITTEE REPORT

Chairman—Dudley Demarest

The Committee met twice in the past year and continued work on several projects and began several new ones. The committee members worked on the Policy and Procedure Manual and the New Member and Graduating Senior Pharmacy Student Kits. This "Survival Kit" project is now being jointly compiled with the Membership Committee.

The committee has begun work on revising the "Salary and Fringe Benefit Survey" instrument so that data entry and analysis will be easier and reporting more timely.

The April issue of the "Maryland Pharmacist" premiered the Employee/Employer Forum. This column will be published at least every other month and will address issues of importance to employees and employers. The first two columns have addressed the several issues that were brought to the committee's attention: those of sick leave and benefit problems due to the non-contractual nature of many positions, and pharmacists' overwork in pharmacies with large prescription loads and impact on patient care. The column will hopefully stimulate its discussion and comment on issues affecting patient care and practice setting as well as work conditions and compensation. I urge all pharmacists, regardless of employment, to read over the column and respond to those issues that concern you or write to us about issues that you think should be addressed.

I would like to thank the committee members that have helped this year and again urge those present at the convention to encourage any pharmacists they know who is interested to contact us. Many projects have been shelved for lack of volunteers.

INDUSTRIAL RELATIONS COMMITTEE REPORT

Chairman—Frank Radigan

I will be taking over as Chairman for the Industrial Relations Committee for the 1988-89 year. The committee will continue its efforts to build upon the good working relationship between the Pharmaceutical Industry and Maryland pharmacies. I look forward to working with the Committee members and ask for anyone who is interested in joining this committee to contact myself or the MPhA office. The committee works at good communications between Industry and Pharmacy and to resolve any problems that may arise between the two, thus insuring good relations.

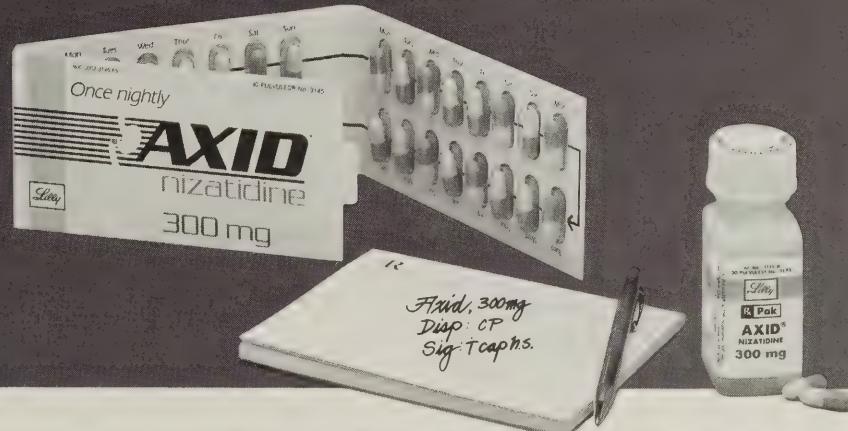


Board of Pharmacy Secretary Moskowitz presents the Board's annual report.

A NEW H₂ Antagonist

AXID® nizatidine 300 mg

Effective once-nightly
duodenal ulcer therapy available in a
Unique Convenience Pak
for better patient compliance



AXID®

nizatidine capsules

Brief Summary. Consult the package insert for prescribing information.

Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within four weeks.

Axid is indicated for maintenance therapy for duodenal ulcer patients, at a reduced dosage of 150 mg h.s. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known.

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H₂-receptor antagonists.

Precautions. General: 1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy.

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatoenzyme syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests—False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine.

Drug Interactions—No interactions have been observed between Axid and theophylline, chlordiazepoxide, lorazepam, lidocaine, phenyltol, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice; although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement

compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, perinatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect, but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates although no studies have been conducted in lactating women. Nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to

determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 U/L), and in a single instance, SGPT was greater than 2,000 U/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antidiuretic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H₂-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs.

Integumentary—Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported.

Overdosage: There is little clinical experience with overdosage of Axid in humans. If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous LD₅₀ values in the rat and mouse were 301 mg/kg and 232 mg/kg respectively.

Axid® (nizatidine, Lilly)

Eli Lilly and Company
Indianapolis, Indiana
46285

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PUBLIC AFFAIRS COMMITTEE REPORT

Chairman: Phillip P. Weiner

The Public Affairs Committee met several hundred times this past fiscal year. These meetings were usually held at 6:15am or 7:30am in the home of the Chairman. The meetings were generally cordial, considering the early hour.

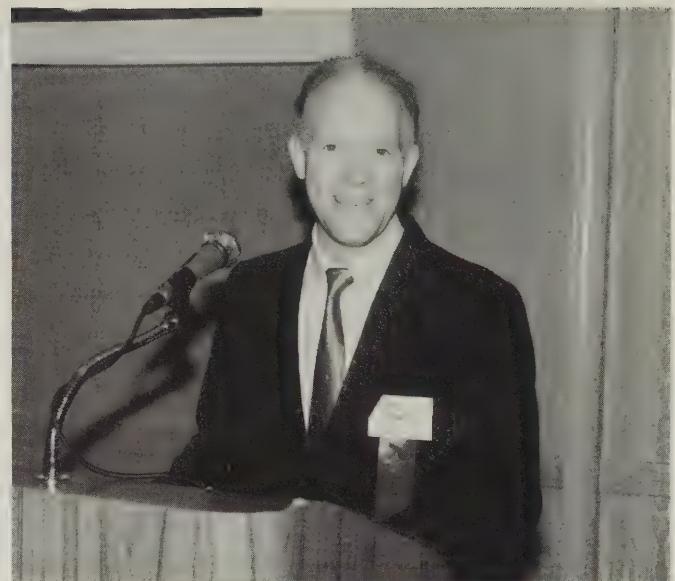
"Your Best Neighbor" was broadcasted twice each Sunday as usual. The times were changed twice during the year reflecting the views of a new program director and the content of the programs. The time slots, I was told, were to be at more advantageous periods.

The public relations project of the MPhA and the USP was a huge success. Alice Kimball of the USP will give you a report on this.

Next year will hopefully bring new interviews to the public discussing as many facets of health care as possible. Submitted respectfully.



Marvin Oed accepts the 1988 Bowl of Hygeia from A. H. Robins representative Paul Mueller.



Outgoing President Lee Ahlstrom was given a round of applause by attendees for keeping MPhA on keel through the past year.

MAFDA COUPON REDEMPTION

Mary Ann Frank

The Mid Atlantic Food Dealer Association (MAFDA) was started in May 1985. The first year 55 stores joined the program.

Currently 83 stores are participating. Rebates up to 3 cents per coupon plus 30 day turn around makes this program attractive.

A profit of \$5101.74 was realized.

MEDICAID LIAISON COMMITTEE REPORT

Chairman—Mark Levi

There is a number of events that have happened in the past year. The effort on the State's part to increase copays and transfer patients to HMOS has been stopped. There is, and will be, an effort to find cost cutting by the state. If we bury our heads in the sand and wait for the problem to go away or shout at the state to complain, this will not solve the situations. It is incumbent upon us to find ways that are least offensive to pharmacy and will save the state the money it is looking for. I look forward to hearing from you many positive ways of offering the state a way to save money.

On a more positive note, there is progress being made on special packaging for prescriptions in the retail setting. Also, there are pending regulations for pharmacists dispensing of condoms on Medical Assistance.

Division of Drug Control Charles Tregoe announces plans to introduce triplicate Rx blanks in Maryland.

A black and white photograph of Charles Tregoe, a man in a suit and tie, speaking into a microphone. He is gesturing with his hands as he speaks. The background is dark and out of focus.



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3. ARE YOUR HEALTH AND BEAUTY AIDS PRICES COMPETITIVE?
4. IF SO, ARE YOU TELLING YOUR CUSTOMERS?
5. HAS INCREASED THIRD PARTY PRESCRIPTIONS AND COMPETITION AFFECTED YOUR PRESCRIPTION DEPARTMENT PROFIT?
6. ARE YOU TIRED AND CONFUSED FROM SEARCHING FOR THE BEST SOURCE OF SUPPLY, AT THE BEST PRICE, TO FILL YOUR O.T.C. AND PHARMACEUTICAL NEEDS?
7. ARE YOU INTERESTED IN A TOTAL PROGRAM THAT WILL SOLVE ANY OR ALL OF THE ABOVE?

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PATRICK L. HRUZ
SALES MANAGER

MARYLAND DRUG UTILIZATION REVIEW PROGRAM

David G. Miller—Director

In March of 1984, the Maryland Pharmacists Association in conjunction with Health Information Designs submitted a proposal to design, implement, and operate a Drug Utilization Review Program for Maryland Medicaid recipients. This program's goal is to reduce Medicaid's drug program expenditures by identifying patients at risk for developing medication induced or aggravated illness.

In February of 1987, the professional review committees began meeting and examining patient profiles identified by a sophisticated analysis system created by Health Information Designs. Since then, regional committees have reviewed between 1,500 and 3,000 profiles a month. These reviewers have already identified more than 1,300 patients in "high risk" cases.

Once a case is identified, therapeutically oriented information letters are sent to providers—physicians, pharmacists, patient clinics, etc.—who are involved in the patient's care. All providers are encouraged to respond to these letters and cases are followed-up periodically to see if the problem has been resolved.

Medicaid renewed the DUR contract with MPhA in July of 1987 with funding to run from September 1 to June 30, 1988. In December, I replaced Jean Hoffman, who was instrumental in getting the DUR program off the ground. Our greatest accomplishment this year has been the automation of the day-to-day functions of the DUR office. This has enabled us to increase the monthly workload without sacrificing efficiency. Also, it has provided us with an excellent working database—this database can be used to enhance the value of the program to Medicaid.

At the end of January 1988, MPhA and HID made its first joint annual presentation to Medicaid and HCFA representatives on the cost savings of the program. Although the actual dollar figure saved is confidential and can only be released by Medicaid, it did show that the DUR program was successful.

By law, the DUR contract must now be placed on competitive bid. The Association is currently in the process of responding to a "Request for Proposals" from Medicaid to keep the contract. Until the new contract has been awarded, the DUR program will probably continue to operate under an emergency contract extension. The Association believes that our bid proposal will be favorably reviewed because of our proven abilities to provide Medicaid with a quality cost saving program.

ACKNOWLEDGEMENTS

The continued success of the DUR program is directly attributable to the hard work and dedication of the review committee members. I would like to personally thank each of the following reviewers for their invaluable assistance.

REGION ONE (Baltimore Metro)

Richard Baylis
Jerome Fine
Paul Freiman
Daniel Harris
Glenn Lichtman
Ilene Maier
Ilene Zuckerman

REGION TWO (Eastern Shore)

Stephen Disharoon
Elizabeth Dixon
James Edwards
Dennis Ferguson
Joseph Jordan
Lane Wroth

REGION THREE (Western Maryland)

Jeffrey Cowen
Patricia Grunwald
Susan Higgins
Joseph High
Michael Rudman
James Rutten

REGION FOUR (Washington Metro)

Raymond Benack
Regina Carson
Murhl Flowers
Gary Magnus
Richard Reitz
Jeannette White

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**PREScription NETWORK
OF MARYLAND**
President: Lee Ahlstrom

The Prescription Network of Maryland, a wholly owned-for-profit subsidiary of the Maryland Pharmacists Association has just completed its first full year of operation. Much of this year was spent establishing the participation levels and geographic distribution necessary to compete for third party contracts.

On March 1st of this year, we signed our first contract with CareFirst to supply pharmaceutical services to their almost 100,000 members. This contract was essential because it gave us instant credibility and also enabled us to implement the use of our state-of-the-art on-line eligibility verification system. The EVS system not only gives us a marketing tool of interest to mature HMO's with problems due to nonmembers using expired cards to obtain prescription coverage, but it also positions us to have the capability of obtaining contracts with companies using major medical programs. The "black box" can track deductables and percentage co-pays so that members, after reaching their deductible, would pay only their deductible when the prescription is filled and their company would be billed for the balance. It has also become invaluable when Medicare's Catastrophic Prescription coverage is enacted and can serve as a credit card verification system.

Other major accomplishments of PNM were the lengthy negotiations with Blue Cross of Maryland that resulted in the Plus Program being presented at the convention. This joint program was developed as an alternative to the establishment of a joint venture mail-order operation between Blue Cross and a major national mail-order firm. It is imperative that community pharmacy cooperates with PNM and BC to make this a success or a Blue Cross-promoted mail-order option in the future is a very real possibility.

PNM is also working hard for mandatory collection of co-payment. CareFirst has agreed to this provision and we are working with other major HMO's to curtail this practice. We have secured a letter of intent with CIGNA and hope to have an agreement with them in the near future.

In summary, I think our first year has been very productive. PNM has demonstrated that it can service the prescription requirements of any provider within the state and also is flexible enough to create new and innovative programs to enable community pharmacies to compete in an ever-changing marketplace.

A great deal of appreciation goes to the staff at the MPhA office for their efforts and dedication that helped PNM become a success.

Good business fact #2



Sandoz can help if "lightning" strikes

It would be hard to find a better catastrophe protection policy than ours. In the event of a flood, cyclone,

hurricane, or other uninsurable catastrophe, we'll go the extra mile to replace Sandoz products you've lost. Our policy is designed to help keep your business afloat. See your Sandoz or Dorsey representative for complete details.

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East Hanover, NJ 07936

Anatomy of a Negotiation Prescription Network News

Melvin Rubin, P.D.

Last fall, Blue Cross sought approval from the Insurance Commissioner for a new program called PLUS. Intended to help fill the Medi-Gap in senior citizen insurance, PLUS makes discount services on vision, hearing, dental and pharmacy services available for a monthly fee.

The pharmacy service proposed by Blue Cross was a mail order option with a guarantee of the lowest available price or the difference back.

To no one's surprise, MPhA testified against that portion of the program, noting that seniors need face-to-face medication counseling more than any other age group, that business would be leaving Maryland, and that this would undermine the existence of community pharmacy services. Rosalie Abrams and the Office of Aging supported our position as did senior citizens themselves.

We threw the challenge to Blue Cross to work with us in setting up a program. When the Insurance Commissioner denied their request on technicalities, the Direct Marketing Department of Blue Cross approached us to do just that—work with them.

Their marketing goals were to offer seniors the lowest price available on these services. Ours was to offer the most services available. From these two points we began to develop a plan.

The players were Linda Benedict, Vice President of Direct Sales, and Garry Raim, Director of Marketing for Blue Cross and a variety of players for PNM including Lee Ahlstrom, Paul Freiman, Dave Banta, and myself. Aid and marketing expertise was given by PNM's consultant Charles Schmidt of Health Services Plus.

An initial program of value added services was quickly decided upon and refined as time progressed. The program was based on professional services already available in many community pharmacies now: promoting generics, reviewing patient profiles advising patients on proper medication use, and drug interaction information. In addition, convenience services such as free delivery and check cashing were added on a pharmacy option basis.

These two options are based on reasonableness. Being considered are—free delivery only in your trading area, no third party checks, no questionable checks from small unknown businesses, no checks from people who had already exhibited bad credit, and right to limit the amount of money kept on hand. Bear in mind, that a bonafide request turned down may cause the participating pharmacy to lose a patient.

Since one senior concern is Durable Medical Equipment (DME) and the bother of having to submit claims for reimbursement, we agreed to offer an option to pharmacies to be listed as accepting assignment, based on reasonableness. This may be modified, for example, if the patient has not met his deductible or if the patient cannot be reached if the claim is denied, or for other good business practices.

Blue Cross was impressed by the USP book *About Your Medicine* and agreed to pay for a copy for each participant to be distributed through the pharmacies. Charles Schmidt agreed to put together a coupon booklet offering discounts on patent medicines as well as \$2.00 off coupons on prescriptions. The coupon booklets will be provided to PLUS participants on a quarterly basis.

Negotiations then reached a critical point. Blue Cross wanted an "aggressive program" (read deep discount). We wanted the value added services to be the selling point. Since they were marketing PLUS as a money saving program, we could not ignore price. The final agreement of a standard 10 percent off prescriptions was fortified by adding an additional five percent off generic prescriptions and guaranteeing the lowest price. Lowest price means that if within 30 days, the patient can show that a competitor in your area offers the same prescription at a lower price, you must refund the difference. Mail order drug prices need not be considered. Some details are still being worked out. Difference-back offers generally are more of a successful marketing tool and patient confidence builder than a cost factor.

The new Blue Cross PLUS program is a genuine plus for community pharmacy. Mail order is not anticipated as a factor if this program succeeds, but for a very little commitment in money, you can receive advertising to as many as 100,000 Maryland seniors.

Attention All Pharmacy Owners...

The Mayer and Steinberg/Maryland Pharmaceutical Association Workers' Compensation Program has always been the best way to purchase your Workers' Compensation Insurance.

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This and That About Pharmacy

Leon Weiner, P.D.

LOVE AND MARRIAGE . . .

** Andrew Barry Pollekoff, son of pharmacist Sheldon E. and Janet Pollekoff married Patricia L. O'Donnell in May 1988. Shelly is one of the pharmacist owners of Alameda Pharmacy in Baltimore City.

** Pharmacist David Oken and wife Davida have announced the engagement of their daughter Robin to Brian Rubin. Robin is a graduate of the UM School of Nursing and Brian is a sales representative for Northern Pharmacy and Medical Equipment. Dave is the owner of Oken's Pharmacy in East Baltimore.

** Nikki Newcomer ('86) found the man to 'light up her life' when she married electrician Edward Phelps in May. Nikki is working for Giant in Greenbelt.

** William Edward Forrest ('86) of Owings Mills was recently married to Kathleen Marie Wissmann at the Loyola College Chapel.

CONGRATULATIONS . . .

To: Marty and Judy Mintz who became grandparents on March 20, 1988 when daughter Mindy ('86) gave birth. Four days later, Marty ('65) was notified that he would be the 1988 Honored Alumnus for the UM School of Pharmacy Alumni Association.

To: Arnold "Skip" Amass who received the Humanitarian Award from the Arlene Rosenbloom Wymann Guild on February 6, 1988. For the past 15 years he has worked on the local, state and national level for the American Cancer Society.

NEW PHARMACIES:

Rite Aid #3829
Route 50 and 611
Ocean City, MD 21842

Giant Pharmacy #1197
7944 Honeygo Boulevard
Baltimore, MD 21236

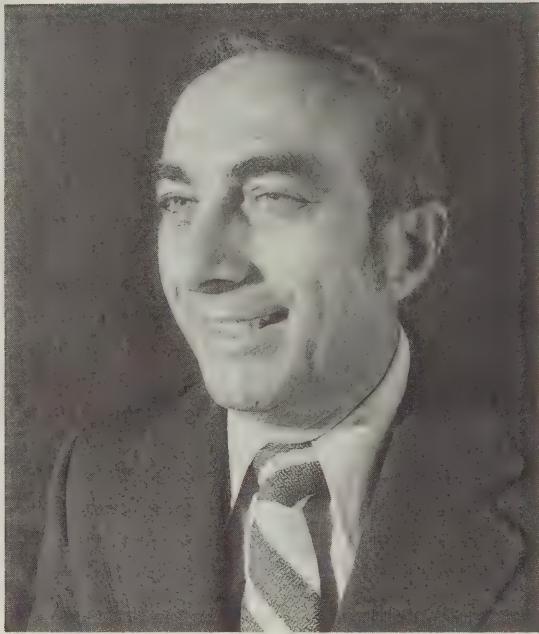
F & M Pharmacy #60
8710 Liberty Plaza
Randallstown, MD 21133

PHARMACY CLOSINGS:

Dart Drug #234
5110 Nicholson Lane
Kensington, MD 20895

NAME CHANGES:

Ocean Drug
14310 Coastal Highway
Ocean City, MD 21842
(Formerly Fenwick Pharmacy)



** Murray Spear ('59) has announced the marriage of his daughter Deborah Lynn to Steven Bowers. Murray is employed by Giant.

** Sylvia Glazer ('83) and Dr. Richard Haber were married in April 1988. Sylvia is a pharmacist and Dr. Haber a resident in psychiatry at Sheppard Pratt Hospital in Towson.

To: Jerry Kirson ('33) and Wayne Dyke ('68) who won big in the Lotto Game of January 30, 1988. Jerry works with his pharmacist son Donald at the Kirson Drug Co. and Wayne is a supervisor for Rite Aid.

To: Thomas E. Patrick ('55) who became the 1988-89 president of the UM School of Pharmacy Alumni Association. Tom is now employed by University Hospital Pharmacy. Years ago, Tom was a sales representative for Upjohn.

NAME AND OWNERSHIP CHANGES:

Berea Health Center Pharmacy
2900 East Oliver Street
Baltimore, MD 21213
(Formerly Johns Hopkins Health Plan)

NECROLOGY REPORT
UNIVERSITY OF MARYLAND PHARMACY ALUMNI
DECEASED ALUMNI—SINCE JUNE 1987

| NAME | DEGREE | YEAR | | | |
|--------------------|------------------|------|---------------------------|-------|------|
| Edward J. Alessi | Ph.G. | 1931 | Irving O. Galperin | Ph.G. | 1932 |
| Silvio A. Alessi | M.D. | 1935 | Isidor H. Gressor | Ph.G. | 1930 |
| Marilyn I. Arkin | Ph.G. | 1925 | Warren A. Gronert | B.S. | 1950 |
| Charles C. Barone | B.S. | 1975 | L. Louis Hens, Jr. | Ph.G. | 1932 |
| Noel J. Bosch | B.S. | 1955 | Morton Kahn | B.S. | 1947 |
| Stephen Chick | B.S. | 1950 | Lester N. Kolman | Ph.G. | 1933 |
| Nathan Cohen | Ph.G. | 1924 | David Leftin | B.S. | 1935 |
| Samuel Cohen | Ph.G. | 1934 | Raymond Lichter | B.S. | 1955 |
| Lester S. Corrick | Ph.G. | 1918 | Joseph Papiermeister | B.S. | 1950 |
| Lillian L. Darago | M.S. | 1962 | Benjamin F. Pickett | Ph.G. | 1925 |
| Katherine B. Easom | Ph.D. | 1967 | Harry L. Rochester | B.S. | 1939 |
| David I. Estrin | B.S. | 1978 | Bernice H. Ruskin | B.S. | 1938 |
| William C. Faith | Associate Member | | | M.S. | 1940 |
| Melvin L. Floyd | M.S. | 1977 | | Ph.D. | 1946 |
| Irving H. Folus | B.S. | 1938 | William J. Schmalzer, Jr. | Ph.G. | 1933 |
| Carroll P. Foster | B.S. | 1939 | M. Martin Settler | Ph.G. | 1939 |
| | B.S. | 1936 | Stuart Shpritz | B.S. | 1948 |
| | Ph.D. | 1942 | Joseph Silberman | Ph.G. | 1932 |
| | | | Irving Topchik | Ph.G. | 1925 |

PHARMACY PASSINGS. . . .

Victor Jerome Sugar ('50) passed away on May 21, 1988, one day after his 60th birthday. After graduation, Vic worked for Read's Drug and later had his own store, Sugar's Pharmacy on Alameda and Kennedy Avenue in Baltimore. For the last 10 years, Dr. Sugar was a state employed pharmacist, first at Mt. Wilson Hospital and then at the Walter P. Carter Center. As a state employee, Vic and his wife Irene were very active with the Maryland Classified Employees Association. He was President of Chapter 32 from the Carter Center and his wife is president of Chapter 13—State Health Department. In addition, Victor was the Area #1 Vice Governor for the last four years.

Nathan Cohen ('24) passed away on March 7, 1988. He owned and operated three pharmacies in the Baltimore area: Westport Pharmacy, Howard Park Pharmacy and Flom's Pharmacy. Along with others, he is survived by pharmacist son Allan ('58-Temple) and pharmacist son-in-law Norman DuBois ('53).

Nathan Levin ('36) died on June 1, 1988. Dr. Levin received his M.S. in 1938 and his Ph.D. in 1941. He was a former Howard University professor of pharmacology and a chemist for Upjohn. Later on Dr. Levin was in charge of the Drug Testing Lab for the Maryland State Department of Health. At the time of his death, he worked part-time as a pharmacist for Rite Aid.

Douglas M. Kadan ('71) died on May 29, 1988 after an automobile accident on Seminary Avenue in Towson. Doug was the former pharmacist owner of Morgan and Millard Pharmacy on Roland Avenue in Baltimore. Later he worked as the pharmacist at Walther Pharmacy. At the time of his passing, Doug worked for the Wyman Park Health System.

George J. Poltilove ('25) passed away on April 12, 1988. He and his brother, Harvey Poltilove ('29) were the owners of Poltilove Pharmacy on Fremont Avenue in Baltimore for many years.

Submitted by Margaret Beatty and Leon Weiner

Standard symbol sought for U.S. pharmacy

Representatives of major national pharmacy organizations have agreed that the idea of developing a standard symbol for pharmacies in this country should be explored further. A meeting was held May 24 at APhA headquarters.

The proposal for a standard symbol was introduced by Irving Rubin in 1986 upon his acceptance of the Remington Honor Medal. Rubin observed, "A symbol is an important piece in the jigsaw puzzle of professional recognition for Pharmacy. By working together and creating 'One Symbol for Pharmacy'—which will be displayed prominently on the exterior of all pharmacies—we will perform a constructive service for the public and the profession."

Fewer than half of pharmacies in the U.S. include any pharmacy symbol on exterior signs. More than 50% of the members of APhA and NARD surveyed at their respective conventions indicated a high level of interest in developing "a single, universally accepted sign of pharmacies."

A worldwide survey of national pharmaceutical associations has revealed that no fewer than 20 countries have adopted a standard symbol or sign for pharmacies. As early as 1936, the "A" for "apotheke" (pharmacy) was adopted in Germany; and in 1942, the green cross with a bowl of Hygeia superimposed was officially adopted by the French.

Since then, countries that have adopted a standard sign for pharmacy include Australia, Austria, Canada (Quebec), Denmark, Great Britain, Hong Kong, Italy, New Zealand, the Netherlands, Nigeria, Norway, Portugal, Spain, Sweden, and Switzerland. The signs vary from green crosses to bowls of Hygeia, from mortars and pestles to the "Rx" symbol.

1988 MPhA Resolutions

The following resolutions were presented, debated and voted on at the Second General Business Session, June 22, 1988. Two additional resolutions, one on AIDS and Syringe Distribution and another on Pharmacy Ownership by Non-Pharmacists were also submitted at the convention. These two resolutions were adopted and text will appear in the September issue of the Maryland Pharmacist.

Resolution One

Whereas pharmacy technicians, and other personnel under the supervision of pharmacy's practice in many aspects of pharmacy in Maryland, and

Whereas standardization of practice for pharmacy technicians and other supportive pharmacy personnel does not currently exist, and

Whereas educational programs for pharmacy supportive personnel may be offered by community colleges without input from pharmacists or pharmacy educators, and

Whereas it is unclear how pharmacy technicians and other supportive pharmacy personnel are being utilized in Maryland.

Therefore be it resolved that the Maryland Pharmacists Association initiate a task force to study the issue of pharmacy technicians and other supportive pharmacy personnel.

ADOPTED—JUNE 22, 1988

Resolution Two

Whereas the main purpose of mass media advertising is to sell a product, and not educate, and

Whereas the advertisement of legend drug products to the general public could increase public demand on prescribers to use or prescribe a specific product, and

Whereas the mass media advertisement of legend drugs is currently allowed,

Therefore be it resolved that the Maryland Pharmacists Association condemn the advertisement of legend drug products by their respective manufacturers to the general public, and

Be it further resolved that the Maryland Pharmacists Association inform the American Pharmaceutical Association of this policy.

TABLED FOR STUDY—JUNE 22, 1988

Resolution Three

Whereas the pharmacist is one of the most respected and trusted health professionals, and

Whereas some printed and TV advertisement of over-the-counter products show persons represented as being pharmacists with opinions or preferences for certain brands of products, and

Whereas pharmacists strive to recommend the most appropriate product for each individual patient with a particular condition even though the product may be out of stock,

Therefore be it resolved that the Maryland Pharmacists Association discourage the portrayal of the pharmacist as biased toward a specific manufacturer's brand in advertising when referring to the population at large with a variety of ailments, and

Be it further resolved that this position be conveyed to the manufacturers utilizing such advertising techniques.

DEFEATED—JUNE 22, 1988

Resolution Four

Whereas veterinarians or other dispensers of veterinary drugs are currently permitted to dispense medications, and

Whereas these medications are frequently dispensed in nonchildproof containers, and

Whereas medications for veterinary use have similar and often greater toxic potential as medications intended for human use, and

Whereas these medications are not subject to labeling or other dispensing regulations by the Maryland Board of Pharmacy, which makes it difficult for poison information center professionals to identify an ingested product,

Therefore, be it resolved that, in the interest of public safety, the Maryland Pharmacists Association supports the concept that dispensers of veterinary medications meet the same reasonable requirements that pharmacists or other authorized dispensers in Maryland are required to meet, specifically with regard to childproof containers, labeling, and record keeping, and

Be it further resolved that the Maryland Pharmacists Association support appropriate regulatory or legislative action to control dispensing of veterinary medications.

ADOPTED—JUNE 22, 1988

Resolution Five

Whereas the Maryland Department of Health and Mental Hygiene has proposed placing Medicaid recipients in managed health care systems (e.g. health maintenance organizations), and,

Whereas it is appropriate to limit freedom of choice of health care providers, including pharmacists, for Medicaid recipients, and

Whereas assignment of Medicaid recipients to managed health care systems with closed pharmacy agreements or arrangements would prevent qualified pharmacists pharmacies from participating in government programs, and deny freedom of choice to recipients,

Therefore be it resolved that the Maryland Pharmacists Association oppose assignment of Maryland Medicaid recipients to managed health care systems with closed pharmacy agreement or arrangements.

ADOPTED AS AMENDED—JUNE 22, 1988

Resolution Six

Whereas problems of tracking the misuse, diversion and illegal prescribing and dispensing of controlled dangerous substance (CDS) exist in Maryland, as in other states, and

Whereas a statewide database of CDS prescription orders would enable more complete identification of specific problems in this area, and,

~~Whereas a triplicate prescription order system would create a financial strain on pharmacists and the Division of Drug Control due to increased paperwork load,~~

Therefore be it resolved that the Maryland Pharmacists Association work with the Division of Drug Control to establish a method of tracking prescription for CDS.

~~And be it further resolved that the Maryland Pharmacists Association opposes the triplicate prescription system as a method for monitoring CDS prescriptions.~~

ADOPTED AS AMENDED—JUNE 22, 1988

Resolution Seven

Whereas reimbursement for prescription drugs under government programs such as Medicaid and Medicare may be limited to designated diagnoses, and

Whereas the prescribers of prescription drugs make the diagnosis for which the drugs are prescribed, and

Whereas reimbursement may be prohibited or limited in any program when the diagnosis is not on the prescriptions,

Therefore be it resolved that the Maryland Pharmacists Association support a policy that the diagnosis should be placed on the prescription by the prescriber.

TABLED FOR STUDY—JUNE 22, 1988

More Convention Highlights From Ocean City

CONTINUING EDUCATION COORDINATING COUNCIL REPORT

Chairman: Madeline Feinberg

As Chairman (the only draft choice for the position), I wish to thank all of the CECC committee members who generously offered their time and expertise to "educate" me about continuing education. Special thanks to Dave Miller who donated his time and energy to help make our programs a big success this year.

CECC sponsored three programs during the past year: a fall program on hypertension, an early spring program on pharmacist malpractice, and a late spring program on the impaired professional. All were well attended and received excellent evaluations.

CECC also co-sponsored two programs offered by Montgomery/Prince George's Pharmaceutical Association. A fall program on benzodiazepines and a winter program on ACE inhibitors were a major success and certainly proved that there is local interest by pharmacists to attend local programs. Thanks to Beverly Yachmetz and Gary Magnus for their initiative in reactivating their local group via the CE programs.

In response to the finalization of regulations on mandatory CE, we have updated the ACPE guidelines for co-sponsorship and will be mailing these guidelines to all affiliated associations. As you know, ACPE is most *strict* with regard to co-sponsorship requirements. There are a myriad of details which must be attended to in a timely manner. Given a *reasonable* amount of notice, the CECC Committee will be delighted to work with any group to help meet ACPE requirements. Unfortunately, this *cannot* be done 3–4 weeks prior to a program, nor after the program has been given!! We therefore ask that groups wishing to offer CE with ACPE co-sponsorship contact us as soon as possible so that the ACPE approval process can be initiated in a timely manner.

In the absence of an Executive Director, the CECC Committee volunteers did an outstanding job and even pulled off a few miracles to be within guidelines for our programs. I wish we could have satisfied everyone. Under the circumstances, we did great! Thank you.

**PHARMACISTS
REHABILITATION COMMITTEE
ANNUAL REPORT**
Tony Tommasello, President

The Pharmacists Rehabilitation Committee was formed in response to a perceived need to establish a middle ground between a pharmacist's dysfunction in practice and license suspension or revocation by the Maryland State Board of Pharmacy. The Committee contracted its first treatment agreement in October 1983. The purpose of the Committee is to intervene and take appropriate action so that the impaired pharmacist can have a chance to address the dysfunction appropriately and save his/her career and preserve their mental and physical well being. The goal is to act as swiftly as possible to insure that the pharmacist obtains proper counseling and medical treatment. Pharmacists who desire the advocacy strength of the Committee must enter into a signed contract with the Committee. Information is maintained in complete confidence, protected by law, separate and apart from any Association or State Board records. Following a successful rehabilitation all records are purged from Committee files.

After a successful fund raising year, as reported last year, the Committee proposed two goals for this year. One was to address the issue of re-entry into practice by the recovering pharmacist. Another was to expand the program so that regions of the state beyond the immediate Baltimore metropolitan area could be served. Obviously the gains made in past years related to committee memberships, financial stability, organizational structure and network development had to be maintained. An ongoing desire is to increase the ratio of self referred to board referred cases.

Regarding the first goal, the Committee will be conducting a pharmacy continuing education program on June 5, 1988 entitled, "Substance Abuse Among Pharmacy Staff: Addressing employee and consumer needs." It explores the concerns facing our profession with respect to dealing with the impaired pharmacist employee. It is hoped that those attending will begin to understand that by becoming part of the recovery process, the pharmacist employer reduces the costs associated with pharmacist impairment. This program is sponsored by the Maryland Pharmaceutical Association and has received financial support from McNeil Pharmaceutical and Marion Labs.

During the year the committee has begun to cultivate employment opportunities for recovering pharmacists. The first inroads have been made in non-dispensing areas of pharmacy practice. Successful placements into drug information services and administrative positions have been achieved.

As for the second goal, the Committee has established a presence in Western Maryland and on the Eastern Shore. This has been accomplished through co-operative efforts with local pharmaceutical associations, tapping the resources of pharmacists who have successfully completed a recovery program, and building a network of qualified treatment providers in these areas. These efforts have spilled over into interstate referrals. The Committee has both received referrals from other states and has made referrals to other state committees when Maryland pharmacists move out-of-state while in treatment.

This interstate activity is bolstered by the active participation of the committee president and chairman in national and regional meetings. Our Committee continues to be a leader among pharmacist recovery programs. Our chairman is the treasurer of the northeast regional organization of similar committees. The president has published an article in the *Maryland Med Chi Journal* issue dedicated to impaired professionals and will be a speaker in their national conference on professional recovery issues.

Our Committee members are well educated in the area of pharmacist recovery issues. Four of the six current committee members have been trained at the Utah Summer Institute section on pharmacist impairment. The remaining two members are scheduled to attend this summer.

The Committee has designed its own stationary with an encouraging logo that captures the spirit of cooperation between the Committee and the pharmacist. We have also revised the contract that lays out the agreement between the Committee and the pharmacist seeking help.

During the year since our last report, 15 contacts resulted in 10 new treatment contracts. Five pharmacists successfully completed treatment. The Committee is following 11 active cases of which 4 are referred by the state board. Unfortunately 2 pharmacists refused to comply with their contract agreement and out of concern for the public welfare they were considered treatment failures and were referred to the State Board of Pharmacy in accordance with the contract terms.

As a result of the generous support of the pharmacy community the committee was able to provide a treatment loan to one pharmacist and to guarantee payment in other cases. These payments were not actually provided because payment arrangements were worked out. However the ability to make the guarantee assured the immediate admission of the pharmacist into the treatment program.

With a solid foundation of financial support the committee will embark upon a program of early identification and treatment by reaching out to students. Two students are being sent to the Utah Summer Institute along with two of our Committee members. The plan is to initiate a peer intervention program for pharmacy students.

In addition to the Utah summer program the committee will undergo specialized intervention training. This should improve the outlook of reducing the number of cases of pharmacist impairment that reach the State Board.

The committee plans more promotional activities through monthly articles in the *Journal of the Maryland Pharmaceutical Association*. Other media will be utilized to publicize the Committee's existence and purpose.

Last year the committee hired a part-time program coordinator, Ms. Henrietta Bond, MHS. Her activity has led to the development of an effective tracking system for following the clinical progress of pharmacists during their recovery period. The committee now is able to maintain closer contact with individual pharmacists, their treatment providers and employers. Funding for this position must be continued and is budgeted currently at \$2400 annually.

Support for the committee was provided by MPhA member dues checkoff and a MSHP contribution. We continue to receive support that is not reflected in the figures below. Sponsorship of committee member participation at educational programs such as the Utah summer institute are provided by an APhA grant and by Pharmacy school support. In addition we receive in-kind assistance from the MPhA and Pharmacy school

for administrative and secretarial support. As the secretarial load increases we will have to provide remuneration for this service. The majority of the workload continues to be handled by the volunteer members of the committee, without whom the program would not exist.

Next year we anticipate greater expenses in the areas of committee member training and secretarial support. We would also like to increase the program coordinator's time so that we can expand our service provision to Western Maryland and the Eastern Shore.

We wish to thank all those who have contributed time, effort, and money to the Committee's work and regret not being able to acknowledge each gift individually in this report. Special thanks are in order to the MPhA, MSHP, and the University of Maryland School of Pharmacy for support.

The Committee recognizes the volunteer time and effort of the following volunteer members of the committee:

Gil Cohen, Steve Cohen, John Davis, Gerry Epley, Harry Finke, Felix Gyi, Tony Tommasello, Keith Walters and Charles Whitfield. We also thank Robert Patti for recent legal consultation.

We would also like to publicly acknowledge the vision of Mr. Dave Banta who worked with the committee in its formative stage and encouraged its development.

Commentary

by Jim Dickinson

I was wrong. Every time a pharmacist is successful in defending a plaintiff's claim that the pharmacist had a 'duty to warn' of potential adverse reaction to prescribed drug therapy another strike is made against the idea that pharmacy is a profession."

So writes R. Tim Webster, executive director of the American Society of Consultant Pharmacists, in response to a recent column that hailed the reversal of *Leesley v. West* in Illinois.

That case, it may be remembered, would have required pharmacists to dispense the manufacturer's professional labeling insert with every prescription. A higher court reversed that ruling, and I described the reversal in the context of "a season for renewal."

Tim disagrees, and he is right. "The only renewal associated with these pyrrhic court 'victories' is a renewal of the contention that pharmacy is only a business of selling drugs," he instructs.

"In short, there is no professionally-rewarding, well-compensated future in simply selling drugs. Only through providing full drug-use information services (patient counseling) and being held responsible for the information provided can pharmacists hope for a renewal of the public's perception of pharmacy as a profession."

This is sound advice. But, like a lot of sound advice it may be hard for some on the frontline of the marketplace health wars to follow.

Take Gary Fragale, of Mannington, West Virginia, who like thousands of independents everywhere is so beleaguered by the deadly combination of third-party payors and discount chains that he's preparing to take out an osteopathic medical degree so that he can provide one-stop, street-front medical services as well as prescriptions.

Or take Marty Rubin, in San Antonio, Texas, who's coming to the bleak conclusion that HMOs will never buy pharmacy's counseling role, unless and until a strong patient demand for it is generated by pharmacists who realize that their independent practice is doomed without it.

What I was attempting to say about *Leesley v. West* was that its reversal provided relief from a progression of decades of oppressive liability burdens on pharmacists, and as such was a sign of a turning tide in liability decisions.

After Tim's rebuke, I went back to Professor David B. Brushwood, J.D., Pharm.D., who had first drawn my attention to *Leesley*.

That's when I learned that I had misconstrued the narrowness of the case. Leesley originally upheld the duty to warn in a context of drug *choice* (i.e., the patient's right to be frightened out of using the drug at all), versus the duty to warn in the context of drug *use* (patient's right to be counseled about utilization issues).

The two are poles apart, Professor Brushwood points out, and although the courts are retreating as I observed from making new law in such matters, a pending case in the Washington State Supreme Court is likely to strengthen the counseling cause by expansively interpreting a 1974 state pharmacy regulation requiring counseling.

Some 12 other states have similar regulations, and they may be expected to follow Washington's lead. Even in the majority of states that now lack such a regulation, such a movement may provoke adoption of similar rules for pharmacists because multi-state HMOs and insurance companies will want uniformity for premium purposes.

Will the profession resist? Professor Brushwood thinks not—except for older practitioners, perhaps, most of whom were specifically educated in their student days *not* to counsel (so it's against their nature now).

When he first began talking to pharmacy groups about counseling over a decade ago, he discerned a generally hostile attitude to its legal dangers. Recently, though, he's observed a generally favorable attitude instead.

All this may be part of Marty Rubin's point. To survive, independents are going to have to make a bold point of, and promote, the value of their counseling capabilities.

Even those who have the least interest in counseling—the mail-order drug companies—are coming to grips with the issue. Medco Containment Services, operator of National Pharmacies, has been trying to sign up selected retail pharmacy representatives to handle some of its counseling needs, and claims a new 24-hour "800" number to give subscribers emergency pharmacist advice.

Does the public *want* to be counseled with every prescription? That may be the \$64,000 question of the decade. Obviously, some do, and some don't. Present attitudes are probably changing, however.

Insurance companies, Medicaid and HMOs won't want to encourage counseling unless a cost-benefit association can be shown—and if it is shown, and they do adopt the need for counseling, their reimbursement may be negative (X% off the present fee if you don't counsel, counseling to be assessed by periodic beneficiary audits/questionnaires).

But with the growing preponderance of elderly and others on maintenance medication, my bet is that counseling by pharmacists will be demand-driven in the near future. Those pharmacists who anticipatively move now will have an advantage.

I was wrong about Leesley, but not, I think, about pharmacy's renewal. Thanks, Tim.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

TOXICOLOGY MEETING ANNOUNCEMENT

1988 AAPCC/AACT/ABMT/CAPCC ANNUAL SCIENTIFIC MEETING BALTIMORE, MD OCTOBER 1-4

The 1988 American Association of Poison Control Centers/American Academy of Clinical Toxicology/American Board of Medical Toxicology/Canadian Association of Poison Control Centers Annual Scientific Meeting will be held in Baltimore at the Marriott Inner Harbor on Saturday October 1st through Tuesday October 4th.

The program includes platform and poster sessions, the ABMT symposium on Carbon Monoxide (morning of Saturday, October 1) and the AACT symposium on Epidemiology (morning of Monday, October 3). A special session on Aquatic Toxicology is planned for Monday afternoon. Continental breakfast will be available each morning from 7:00-8:30 am. A cocktail reception sponsored by Du Pont Pharmaceuticals will

be on Sunday, October 2 from 5:00-7:00 pm at the University Club. The President's Reception, sponsored by McNeil Consumer Products on Monday, October 3 from 7:00-11:00 pm, includes dinner at the National Aquarium in the Inner Harbor.

For more information and registration materials call 328-7604 Monday thru Friday between 9:00 am and 4:00 pm.

The meeting registration fees are \$100 for AAPCC members, \$125 for non-members, and \$40 for full time students and residents. After August 15th, registration fees will be \$125 for AAPCC members, \$150 for non-members and \$65 for students and residents. Continuing education credits for pharmacists are being provided through the American Academy of Clinical Toxicology.

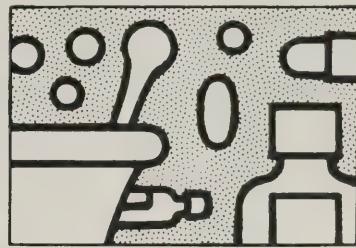
The American Academy of Clinical Toxicology is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. The ACPE universal program number is 187-225-88-01.

Show your patients pharmacy is a service

Do your patients think of pharmacy as a service or as a commodity? If they see pharmacy as a commodity, how can you help them see it as a service?

1. Tell people how your services are different. All the innovative practice in the world won't get you more clients if you don't promote your uniqueness.
2. Follow through on whatever you start. If you discontinue a service or practice, tell people why.
3. Invite patients to seminars on medications or diseases periodically.
4. Establish a patient advisory board and meet with it once a month.
5. Survey the patients in your area to find out what services they're most interested in. Then provide those services.
6. Solicit comments. Send patients a follow-up postcard asking, "How did you like our services?"
7. Act on all feedback—positive and negative—even if you just explain why you can't do something.
8. Increase pharmacist and patient contact by assigning assistants to tedious tasks.
9. Send or give out product information with two tea bags; invite patients to have a cup of tea at home while they read the information.
10. Send a pharmacist to the home to consult with patients on medications.
11. Visit retirement and nursing homes and service organizations; invite residents to bring all their medications to you for counseling.
12. Make your prescription area accessible—put it up front.

Things You Should Know **FOR YOUR GOOD HEALTH**



Lice? Don't Panic

Lice infestations have long been considered a major community health problem. Lice are found everywhere and do not make social, financial, cultural, or geographic distinctions. Although commonly viewed as affecting only the dirty and disadvantaged, this is simply not true.

Lice are easily transmitted from person to person because they and their eggs can survive for short periods of time removed from direct human contact. Outbreaks most commonly occur in the Fall, when school resumes. In fact, estimates suggest that as much as 50% of the millions of lice infestation cases occur during the months of September and October when children return to school. Affected children bring lice home with them, placing the entire family at risk of infestation.

There are three varieties of lice that affect man including head lice (*pediculus humanus capitis*), body lice (*pediculus humanus corporis*), and crab lice (*phthirus pubis*). Most lice are limited to habitats suggested by their names — head lice are found near the scalp and crab lice in the pubic area. Lice found in less hairy parts of the body and are all but extinct in the U.S. are called body lice.

The most prevalent form of infestation is from head lice. Head lice require a warm environment to survive, therefore they are most frequently found no more than one-half inch from the scalp of the host. To supply offspring this climate protection, female head lice deposit nits (eggs) using a sticky, cement-like substance on the hairshaft near the scalp.

Head lice infestation is not life

threatening, no matter how long one has them, and they can be easily treated once detected. A symptom of head lice is persistent itching of the scalp which is sometimes accompanied by what appears to be a rash. Inspection of the scalp will detect silvery capsules containing nits. Otherwise, no other symptoms typically appear.

In the past, treatment of lice infestation required a physician visit. Prescription medications containing lindane in the form of lotion, shampoo, and solution have long been recognized as effective treatments. In recent years, over-the-counter (OTC) preparations which kill lice and their nits have become popular. Effectiveness of these products appears to rival that of the prescription lindane products. Many of the OTCs supply a fine-toothed comb used to dislodge the dead nits. Although removal of the nits is usually not necessary it is cosmetically preferred.

It is generally recommended that if one member of the family is discovered to have lice, that the entire family be treated. This action will help to prevent reinfection among members of the same household. Also recommended in such cases is a thorough washing of bed linens and clothing which may harbor lice or their nits.

Lice infestation is an irritating social problem but does not reflect negatively on your personal hygiene. So if you suspect a member of your family may have developed a lice problem, don't panic.

ASK YOUR PHARMACIST for more information on lice and its treatment. It's For Your Good Health.

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The 1988 MPhA elected officers and trustees.



The Exhibit Hall was well attended. More than forty companies exhibited.



Alice Kimball of U.S.P. announced the findings of the joint pharmacy program conducted with MPhA.



1988 Remington Medalist Peter Lamy at the Annual Banquet.



New Executive Director Greg Wood was welcomed by members.



Ahlstrom presents Donald Fedder with the 1988 Pharmacists Achievement Award for noteworthy service.



Chairman Maddy Feinberg Presents 1988 Honorary President Walter Weglein.



Ilene Zuckerman was elected Speaker of the House of Delegates.

A 1988 Convention Scrapbook



Lawyer Steve Sfekas talks about patient counseling responsibilities.



The Exhibit Hall Ribbon Cutting Ceremony.



Dr. Rob Michocki discussed the importance of NSAID monitoring.



Dr. Dave Roffman lectures on the cardiac therapies.

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SAMPA President Betty Alpern presided over the Brunch and Fashion Show.



Chairman Feinberg and Betty Alpern with plaque of thanks from SAMPA.

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FREE EMPLOYMENT placement service available from the MPhA—Call Beverly at (301) 727-0746.

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

“Rx” LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say “Maryland Pharmacists Association” in addition to “Rx” and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff’s Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

LAMBDA KAPPA SIGMA sorority is planning its 75th Anniversary, August 2–6, 1988 at the Copley Plaza Hotel in Boston. All LKS sisters are encouraged to come and celebrate the future of LKS and women in pharmacy. For details, contact Mary Greer at Lambda Kappa Sigma, P.O. Box 981, Claremont, OK 74018.

LOOKING TO BUY SIROIL, 8 ounce bottles. If you have any still in stock please call 358-1149.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, “Your Best Neighbor,” the oldest continuous public service show in Baltimore.

PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

PHARMACISTS WANTED for part time position in Owings Mills and position for part time pharmacy student. Call 363-1822.

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BVD CRABFEAST is scheduled for the third Wednesday in September from 1:00 to 5:00 p.m. Tickets are \$20.00 per person. Contact Steve Provenza for more information.

NARD CONVENTION will be held October 9–13, 1988 in Atlanta, GA. For information and registration, contact 1-800-544-7447 or (703) 683-8200.

CHIEF EXECUTIVE OFFICER: Missouri Pharmaceutical Association is seeking qualified candidates for position of CEO. Full-time salaried position with some administrative duties for the state PSAO. Send resume, references, and salary requirements to: Search Committee, Missouri Pharmaceutical Association, 410 Madison Street, Jefferson City, MO 65101. Deadline: October 1, 1988.

LUPRON 7-DAY THERAPY Kits for sale at direct prices. Call Stanton Ades at (301) 366-1500.

calendar

August 31—Pharmacy School Begins
Sept. 18–24—National Adult Day Care Week
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October 21—MSHP Annual Seminar
February 5—Tentative Mid-Year Meeting

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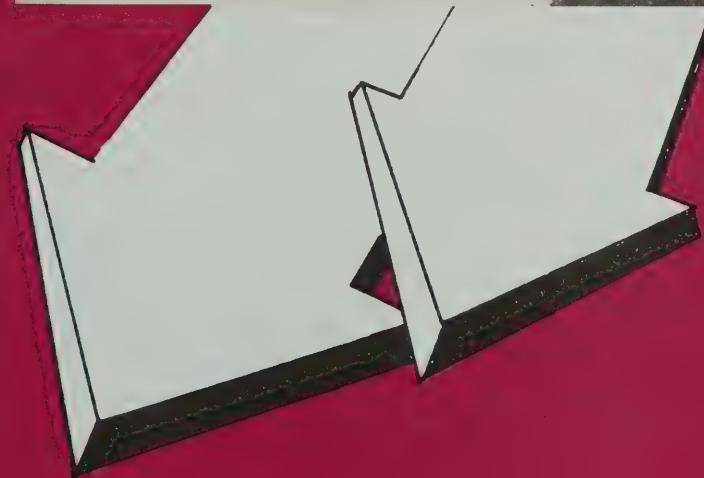
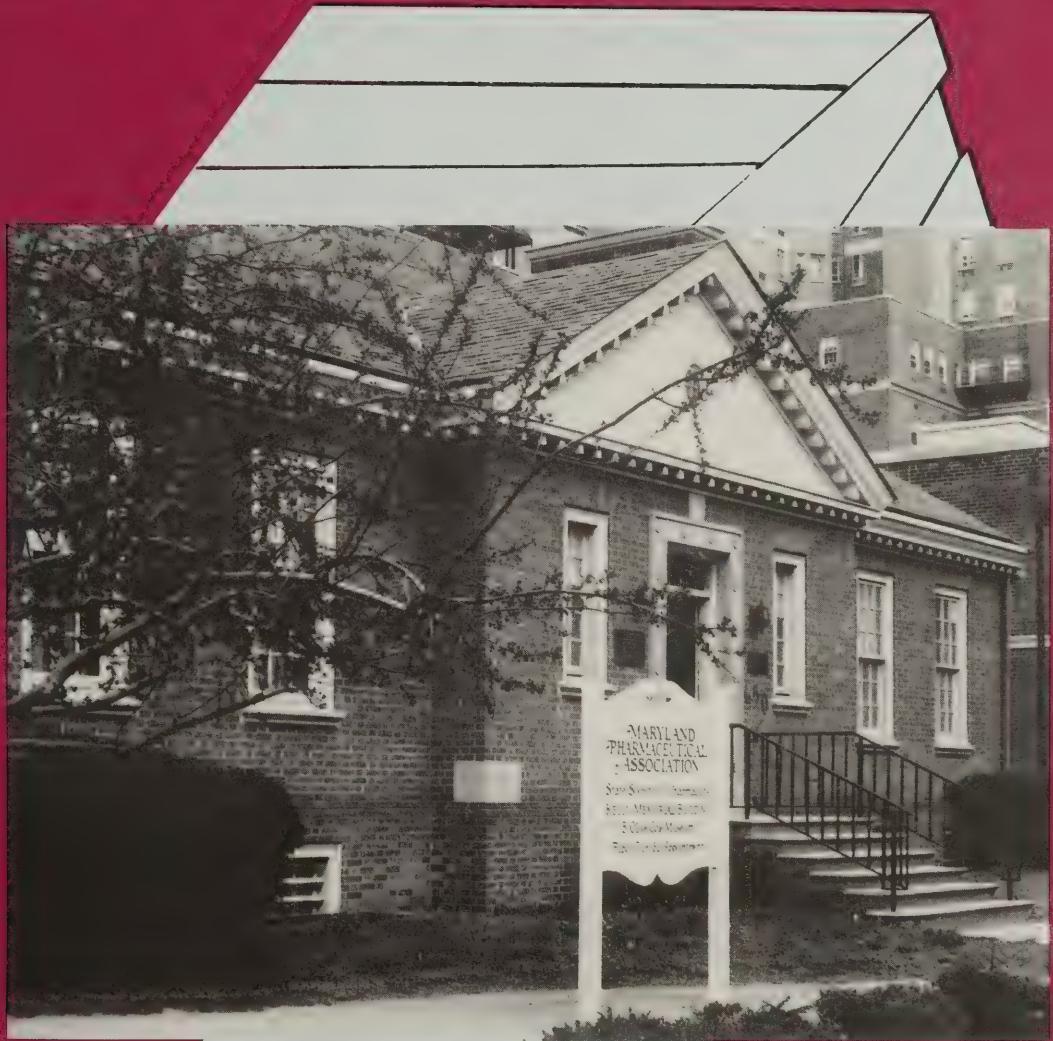
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The Maryland Pharmacist

VOL. 64

SEPTEMBER, 1988

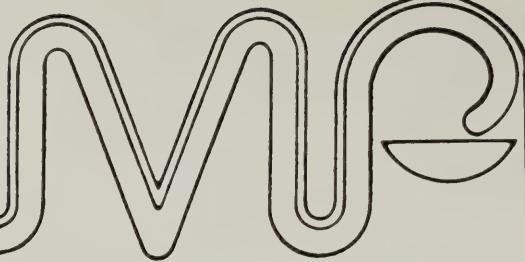
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SEPTEMBER 1988

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Commentary

At its 1988 Annual Convention, the MPhA House of Delegates passed a resolution for initiation of a task force to study pharmacy supportive personnel in Maryland.

Already several national pharmacy organizations are actively studying this important pharmacy issue. ASHP has a Task Force on Technical Personnel in Pharmacy. Although the Task Force has been charged to "think broadly, not restricting itself to institutional practice," all its members have an institutional pharmacy background. At its last convention, the APhA House of Delegates passed a resolution endorsing "the appropriate use of pharmacy technicians," but opposing licensing, certifying, or registering technicians. NACDS favors recognition and use of technicians, but opposes regulation, certifying, licensing or setting ratios. NABP is studying which states license techs. NARD has no position. In 1979, the Association of Pharmacy Technicians was founded in California—they became national in 1981.

Currently, three states require licensing for pharmacy technicians (Illinois, Nevada, Washington) and four states offer certification (Illinois, Massachusetts, Michigan, New Hampshire). Nine states explicitly forbid technicians in community pharmacies. The remaining states either officially recognize techs or do not expressly forbid them (Maryland falls into this category). Maryland is one of 19 states that offers pharmacy tech training programs through community colleges, hospitals, or military, vocational and high schools.

On August 16, the MPhA Task Force on Pharmacy Technicians held its first meeting. The goal of the Task Force is to obtain as much information as possible about how technicians are used in Maryland. To accomplish this, a survey will be included in your October MPhA newsletter. From the results of that survey, the Task Force will present recommendations to the MPhA Board of Trustees.

WE MUST HAVE YOUR INPUT! When you receive the survey, be sure and fill it out and return to the MPhA office. Only through member input can we effectively decide on this increasingly pressing issue facing pharmacy.

Ilene Zuckerman, Pharm.D.

Speaker, MPhA House of Delegates

Chairman, Technician Task Force

Continuing Education

New Drug Update for 1988 Part Two

Beginning with our next issue, the Maryland Pharmacist will include a correspondence quiz to help you earn C.E. credits.



by Thomas A. Gossel, R.Ph., Ph.D.

Professor of Pharmacology
and Toxicology

Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to discuss new drugs approved by FDA and/or marketed in 1987 and 1988.

Objectives

At the conclusion of this lesson, the participant will be able to:

1. demonstrate knowledge of the drugs by pharmacologic and therapeutic classification;



Gossel

Wuest

2. identify their indications, mechanism of action, pharmacokinetic properties, benefits and limitations;
3. identify adverse effects and drug interactions associated with the drugs; and
4. demonstrate an ability to counsel patients on the drugs presented.

This is the second of a two-part series on new drugs approved and/or marketed in 1987 and 1988. Part I discussed cardiovascular and anti-inflammatory agents.

Anti-Infectives

Azactam (aztreonam)

Azactam is the first member of a new chemical class of antibiotics called the monobactams. The monobactam structure contains a monocyclic beta-lactam nucleus and is structurally distinct from other beta-lactams such as penicillins and cephalosporins.

The drug possesses potent activity against numerous gram negative aerobic pathogens. As with other members of the penicillin family, antimicrobial activity results from inhibiting cell wall synthesis. The drug does not stimulate beta-lactamase activity, and is reportedly resistant to hydrolysis by these enzymes. This expands its spec-

trum of activity to penicillinase and cephalosporinase-producing organisms.

Azactam is bactericidal for a wide variety of infections caused by *Citrobacter* sp., *Escherichia coli*, *Enterobacter* sp., *Haemophilus influenza*, *Serratia marcescens*, and other organisms. It is indicated for treatment of susceptible infections of the urinary tract, lower respiratory tract, and skin and skin structures; for septicemia, intra-abdominal and gynecologic infections; and for adjunctive therapy to surgery. Concomitantly-administered aminoglycosides are synergistic against many pathogens.

Patients with a history of hypersensitivity to any penicillin or cephalosporin should be monitored closely if they receive Azactam. Allergic reactions are unlikely, but possible. Probenecid decreases renal secretion, resulting in elevated antibiotic blood levels. Probenecid interacts similarly with other penicillin and cephalosporin antibiotics, but the effect is therapeutically insignificant, unless gonorrhea is being treated.

Bactroban (mupirocin)

This topical antibacterial has a broad spectrum of activity, especially against gram-positive organisms that cause dermal infections. It is structurally unrelated to any other antibiotic. Current data indicate that it is a safe and effective alternative to other topical antibiotics for impetigo and similar dermal infections. An advantage is that it has not demonstrated the hypersensitivity reactions seen with neomycin.

Cefmax (cefmenoxime)

A third generation cephalosporin, Cefmax shares a similar therapeutic profile with other members of this group. Since there are numerous oth-



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er third generation cephalosporin products on the market, the role and place for Cefmax remains to be seen.

Cipro (ciprofloxacin) and Noroxin (norfloxacin)

These "second generation" quinolones are the first of a series of similar broad-spectrum fluoroquinolone antibacterials. Earlier marketed quinolones include NegGram (nalidixic acid) and Cinobac (cinoxacin). Cipro and Noroxin have much greater antimicrobial activity. Also, the potential for development of resistance is greatly reduced as compared to older drugs.

Both drugs are bactericidal against a broad spectrum of gram positive and gram negative organisms including *Citrobacter freundii*, *Proteus* sp., *Pseudomonas aeruginosa*, *Staphylococcus* sp., and *Streptococcus* sp. Ciprofloxacin is claimed to be about four times more active than norfloxacin in *in vitro* studies.

Both drugs bind to the bacterial enzyme DNA gyrase (Figure 1), inhibiting its activity. Since this enzyme converts relaxed (inactive) DNA into its structurally active (supercoiled) form, the quinolones terminate the conversion, and therefore kill the bacteria.

These agents reportedly have few adverse effects. Approximately 3 to 9 percent of patients in clinical trials experience headache, nausea and vomiting, diarrhea and dizziness, but this is considerably less than that seen with nalidixic acid.

Cipro and Noroxin are administered orally. This is important because both products are being vigorously promoted as being safer, more convenient, and less expensive than traditional injectable antibiotics used against these organisms. In the era of cost containment, this should be a powerful marketing tool for hospital and nursing home patients.

Lamprene (clofazimine)

Lamprene is indicated for treatment of *Mycobacterium leprae*, the organism that causes leprosy. It is also used to treat a wide variety of other difficult-to-manage infections, including certain opportunistic ones associated with AIDS. The drug binds to mycobacterial DNA and its

action is bactericidal. By an as yet unidentified mechanism, Lamprene also imparts anti-inflammatory action on the nodules of leprosy.

The drug is reported to cause a number of adverse reactions. Dermal pigmentation appears in a significant number of patients within a few weeks of treatment. In Caucasians, the skin often changes to a pink-red, then brown-black coloration. Conjunctiva, tears, sweat, urine, and feces may also be colored. This is reversible upon discontinuation of the medication, although return to normal skin color may require months to years.

Lamprene is taken orally in doses of 100 to 200 mg/day. When used for the treatment of leprosy, it is often given in combination with dapsone.

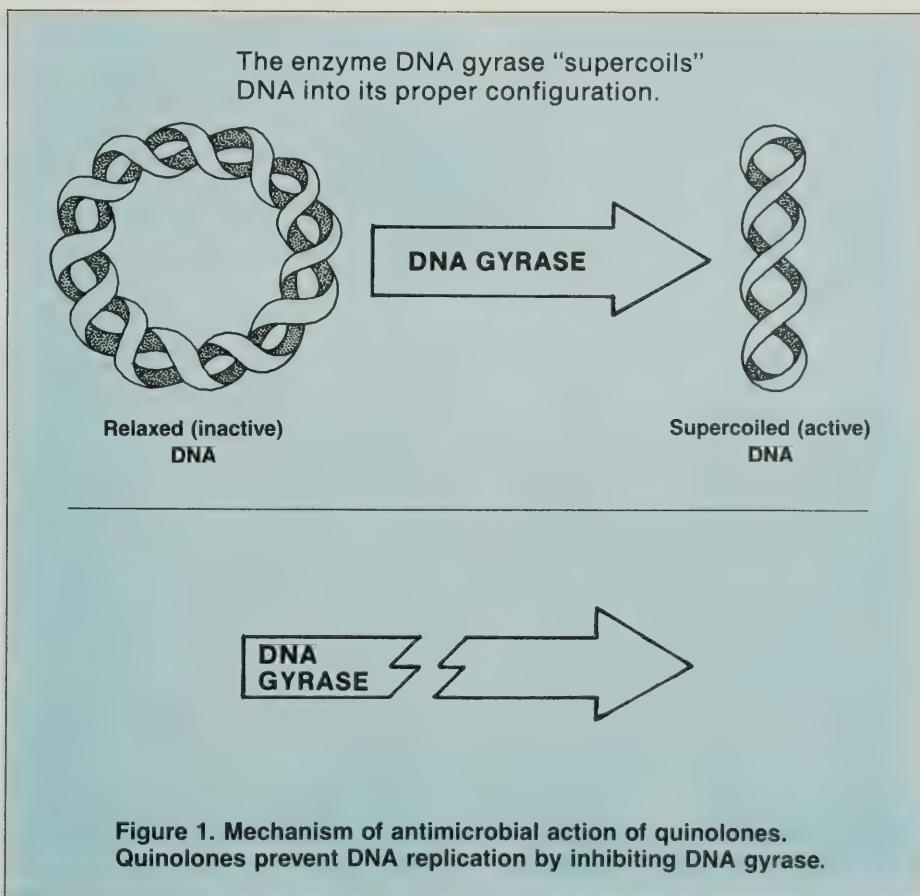
Retrovir (zidovudine)

Formerly known as azidothymidine (AZT), zidovudine is the first drug in the U.S. officially indicated for the treatment of AIDS. Its generic name was changed because another substance had previously been assigned that terminology.

To briefly explain its mechanism of action, thymidine is one of the four nucleotides that occurs in all strands of DNA, including those of the AIDS virus (HIV - Human Immunodeficiency Virus), and humans. With Retrovir, the hydroxy group contained in thymidine has been replaced with an azide group. Retrovir is enzymatically incorporated into DNA by retroviral transcriptidase of the HIV. Because of its structural dissimilarity to thymidine, DNA replication is thereby terminated and viral growth halted. Human DNA polymerase is likewise affected, but the drug has a preferential affinity for the HIV enzyme, reportedly being 1000 times greater than for human cell DNA replication.

Retrovir treats, not cures, AIDS. Patients can still develop opportunistic infections. Because of this, they should report any changes in health to their physician. However, Retrovir-treated patients live longer and enjoy a greater quality of life during the period of treatment. Many treated AIDS victims have lived longer than expected.

The drug does produce toxicity.



Paramount are blood dyscrasias including granulocytopenia and anemia, which can limit therapy. This can also greatly increase the cost of an already expensive therapy due to the need for blood transfusions. Subjective responses most often reported are nausea and headache. Both occur in over 40 percent of patients, but they are also common symptoms experienced by nontreated AIDS victims.

Drug interactions have been reported. Two that must be considered include other drugs that depress bone marrow function (e.g., nephrotoxic and cytotoxic drugs such as antineoplastics and immunosuppressants); and drugs that affect the glucuronidation of zidovudine. The latter group includes acetaminophen, aspirin, indomethacin, and probenecid. This interaction provides an opportunity for patient counseling since persons receiving Retrovir should be informed not to self-medicate for pain, headache, and fever. Ibuprofen has not been implicated in this interaction but the physician should be the judge as to whether it is an acceptable alternative.

To be effective, compliance, while difficult, is absolutely essential. Retrovir must be taken without interruption, 200 mg every 4 hours around the clock.

Terazol-7 (terconazole)

Terazol-7 belongs to a group of antifungal agents called the triazoles. While similar to the other dozen or so "azoles," they may have greater activity against candida and tinea organisms. Terazol-7 is indicated for treatment of vulvovaginal candidiasis. Comparative studies with the drug indicate that it is equal to or more effective than older drugs such as clotrimazole and ketoconazole.

Unasyn (ampicillin/sulbactam)

This product combines a beta-lactamase inhibitor (sulbactam) with ampicillin. It joins a growing list of similar products (amoxicillin/clavulanate potassium — Augmentin; ticarcillin/clavulanate potassium - Timentin) that combine an enzyme inhibitor with an antibiotic. Other

products containing these or other beta-lactamase enzyme inhibitors, with other penicillins or cephalosporins, will probably follow in the future. Adding a beta-lactamase inhibitor to a penicillin or cephalosporin antibiotic reinstates their effectiveness against bacteria that have become resistant.

Unasyn is indicated for parenteral treatment of infections caused by penicillinase-producing organisms that are susceptible to ampicillin. Sulbactam is only weakly antibacterial; its purpose is to preferentially bind with beta-lactamases, thereby sparing the antibiotic from degradation.

Respiratory Drugs

Atrovent (ipratropium)

A synthetic quaternary ammonium derivative related chemically and pharmacologically to atropine, Atrovent is an anticholinergic agent that blocks acetylcholine at peripheral cholinergic receptor sites. A pharmacologic response to such action is relaxation of bronchial smooth muscle. Thus, Atrovent, administered by aerosol inhalation, is indicated for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disorders. It is not intended to be used to reverse bronchospasm where a rapid response is needed. The adrenergic bronchodilators (e.g., Alupent, Bricanyl) are agents of choice for that.

Since it is administered by inhalation, Atrovent is not absorbed to any great extent. Systemic adverse reactions are consequently minimal. Ones that have been reported include nervousness (3 percent), dizziness and headache (2 percent), and nausea (3 percent). There are reports indicating that dry mouth occurs in some patients using the drug, but no where near the level seen with systemically administered atropine-like drugs.

Prolastin (α_1 -proteinase inhibitor)

Produced by recombinant DNA technology, Prolastin is used for selected cases of emphysema. The drug is aimed at a small group of em-

physema patients whose disorder is due to a genetic deficiency. There are probably less than 27,000 Americans with this condition.

α_1 -proteinase inhibitor is naturally produced in the liver of most people. It circulates through the body in the blood, functioning to inactivate elastase, an enzyme that helps destroy bacteria in the lungs. When the enzyme is deficient, elastase is left unopposed and attacks lung tissue, destroying its elastic properties, and severely reducing the lung's breathing capacity. Prolastin corrects the deficiency and alleviates the emphysematous condition.

Miscellaneous Agents

Deursil (ursodiol)

This agent dissolves cholesterol-based gallstones. It joins chenodiol (Chenix) and mono-octanoin (Moctanin), two other drugs indicated for this use.

Like Chenix, Deursil is administered orally. Moctanin is administered directly into the gallbladder by retrograde infusion using tubes inserted therein. In the gallbladder, Deursil interferes with cholesterol binding, thereby dissolving the stones. It, and the others, are only effective for gallstones that are primarily composed of cholesterol, rather than those with high calcium content. This can be easily determined by x-ray. The calcium-dominant stones show up as dark solid objects while cholesterol stones are translucent. Patients with the latter type who cannot or will not undergo gallbladder surgery are candidates for Deursil.

Iopidine (aplonidine)

Aplonidine reduces intraocular pressure. The ophthalmic solution is indicated for reducing intraocular pressure spikes that occur following laser eye surgery.

Humatrope (somatropin)

Somatotropin (growth hormone) and its synthetic analogues promote skeletal, visceral, and general body growth. A deficiency results in pituitary dwarfism; excessive hormone

causes gigantism. Unlike some other endocrine hormones, growth hormone is species-specific. This means that replacement hormone must be obtained from the pituitary gland of human cadavers rather than animal sources.

In May, 1985, manufacturers of human pituitary-derived somatotropin announced that these products would be discontinued because of the possibility that they transmitted a rare, lethal virus. Shortly thereafter, somatrem (Protropin), a growth hormone product of recombinant DNA technology, was approved and marketed.

Somatropin, a similar but slightly different analogue of human growth hormone produced by recombinant DNA technology, has now entered the market for use in children with endogenous growth hormone deficiency. It is not intended for use in adults, or for any purpose other than replacement therapy.

Metrodin (urofollitropin)

This gonadotropin is indicated for reversing infertility in patients with the polycystic ovarian syndrome (POS) who fail to respond to clomiphene. The POS is characterized by an improper LH/FSH ratio. Briefly, FSH (follicle stimulating hormone) causes graafian follicles to form and grow. LH (luteinizing hormone) stimulates further growth, maturity, and release of the developed egg into the fallopian tube. Women with POS ovulate immature ova which cannot be fertilized by sperm. Since urofollitropin stimulates ovarian follicular growth, the resulting ova are mature and hopefully, capable of fertilization.

As with previous fertility agents (i.e., Clomid, Pergonal), multiple ovulations and pregnancies are possible. In clinical trials, 17 percent of pregnancies resulted in multiple births.

The drug is administered IM once a day for 7 to 12 days. The day after the last dose of urofollitropin, a dose of human chorionic gonadotropin (hCG) is given to initiate ovulation.

Novantrone (mitoxantrone)

Novantrone is officially indicated for treatment of nonlymphocytic leukemia. However, it is also being used

outside the U.S. for breast cancer and is marketed for that purpose in 35 other countries. This may eventually be an indication in this country as well. Promising results are also reported for Hodgkin's disease.

The precise mechanism of pharmacologic action is unknown. Like doxorubicin, mitoxantrone cross-links with DNA between base pairs of the DNA double-helix, inhibiting nucleic acid synthesis.

ProHIBIT (Haemophilus b conjugate)

Haemophilus influenzae type b is a primary cause of meningitis in children under age 5 years. The new conjugate vaccine is indicated for prophylaxis of infections in children 18 months to 5 years. It appears to more actively stimulate the body to produce antibodies against Haemophilus organisms than previously available vaccines. It is the first such vaccine to be approved for use in children under 2 years of age, and its manufacturer is reportedly awaiting approval for use in children 6 months of age, and possibly younger.

Prozac (fluoxetine)

Since it has become vogue to refer to newly developed drugs as being "second" or "third" generation entries, similar terminology can be applied to Prozac as well. The first generation antidepressants were the tricyclics (e.g., Elavil, Tofranil); second generation drugs were Asendin, Desyrel, and Ludiomil.

It has been speculated, and there is supportive evidence, that some depressed patients have lower levels of serotonin within the CNS. Interestingly, autopsies of persons who committed suicide showed a significantly lower concentration of serotonin in their bodies as compared to other persons who died of natural causes.

Prozac inhibits neuronal uptake of serotonin within the CNS. It also reduces uptake of serotonin into its other major storage compartments—platelets. It has no effect on norepinephrine or dopamine. The biogenic amine theory of affective mental disorders holds that if depression is caused by insufficient extracellular serotonin, preventing its uptake into

cellular storage sites will correct the imbalance and reverse the depression.

The drug is indicated for the same types of depression as the other antidepressants. It may be an alternative for patients who cannot tolerate tricyclic-induced side effects. Since it does not react with cholinergic and histaminergic receptors, the classic side effects and toxicities of the tricyclics have not been seen.

In clinical trials, and in other countries where it has been available, fluoxetine has demonstrated significant anorexiant (appetite suppressing) effect. This is an interesting phenomenon because depression often leads to overeating, and antidepressants sometimes cause weight gain.

Prozac acts at the same areas of the brain as fenfluramine (Pondamin), but it is even more active. There is strong evidence that Prozac will eventually be used more to treat exogenous obesity than depression given its lack of abuse potential.

Ucephane (sodium benzoate/sodium phenylacetate)

This combination of ingredients is indicated for prevention and treatment of hyperammonemia in persons with deficiencies in urea metabolism. Given by IV infusion, the drug neutralizes ammonia ions (by-products of protein metabolism) and prevents their excessive build-up, increased blood pH, brain damage, and death.

Summary

New drugs approved by FDA and/or marketed during 1987 and 1988 represent a variety of exciting therapeutic agents. Hopefully the new drugs for successive years will be as challenging. 

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Baltimore Pharmacist Honored for Outstanding Community Service

Marvin L. Oed of Baltimore has been honored by the Maryland Pharmaceutical Association as its 1988 recipient of the A.H. Robins "Bowls of Hygeia" Award for outstanding community service by pharmacists.

Oed, clinical assistant professor and director of the professional experience program at the University of Maryland's School of Pharmacy, received the award this evening during the association's annual convention in Ocean City.

Making the presentation was Paul G. Mueller, professional medical service specialist in the Capital Division of the A.H. Robins Company. Participating in the ceremony was Lee Ahlstrom of Edgewater, president of the Maryland Pharmaceutical Association.

Oed's community activities have included conducting free health-care screening for high blood pressure, colon-rectal cancer and diabetes. He also has participated in Poison Prevention Week programs and blood collection drives.

In pharmacy, Oed is a member of the Maryland and American Pharmaceutical Associations, the National Association of Retail Druggists and the American Association of Colleges of Pharmacy. He received his training in pharmacy at the University of Maryland.

The Bowl of Hygeia, most widely recognized international symbol of pharmacy, derives from Greek mythology. Hygeia was the daughter and assistant of Aesculapius (sometimes spelled Asklepios), the God of Medicine and Healing. Her classical symbol was a bowl containing a medicinal potion, with the serpent of Wisdom (or guardianship) partaking of it. This is the same serpent of Wisdom which appears on the caduceus, the staff of Aesculapius which is the symbol of medicine.

The "Bowl of Hygeia" Award is a handsome mahogany plaque measuring 10 by 13 inches and featuring the Bowl of Hygeia cast in bronze. It is modeled after a sterling silver bowl made by a Mexican silversmith and given to A.H. Robins Company by its Latin American representatives in 1953.

A desire to encourage pharmacists to take active roles in the affairs of their respective communities prompted E. Claiborne Robins, chairman of the board, to establish the award in 1958. It is now presented annually by participating pharmaceutical associations in each of the United States, the District of Columbia, Puerto Rico and the 10 provinces of Canada. The recipients are selected by their respective associations.

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Non-Prescription (OTC) Drugs and the Elderly

by Peter P. Lamy, Ph.D.

The Health Care System

The health care system is undergoing a revolutionary change. There will be megacorporations, managed health care systems, cost shifting, demands for less expensive care, HMOs, PPOs, smaller acute care hospitals, a rise of the rehabilitation hospital, and more community care centers, among other changes.

Two factors, are the driving forces in the continuing and unabating escalation of health care costs: (1) the increasingly complex high technology care and (2) the demographic imperative.

The number of elderly (who are the largest consumers of prescription drugs) is rising disproportionately. Furthermore, the aging population, itself, is growing older. There are now approximately 50 million people 55 years old and over in the US, and the population of those 65 and over constitutes 11.7% of the total US population. Between now and the year 2000, the number of 75 to 84 years old will increase from 7.7 to 12.2 million, and the number of the oldest-old, those 85 years and over, will increase from 2.5 million (approximately 1% of the population) now to five percent of the population (approximately 12 million) by the year 2050.

Five percent of the elderly now reside in nursing homes, and to accommodate five percent in the future will demand a doubling of the number of nursing home beds. This does not seem likely. Already, for every person residing in a nursing home, there are almost four persons of equally poor medical status in the community, and that number may rise. Thus, home care is and will most likely remain the fastest-growing sector in the health care market, probably topping \$25 billion in 1995, up from \$6 billion in 1983. There now needs to be concern not only for the home care patient, but also for the family caregiver. Over three million family units provide major physical, personal, or financial help to their disabled elderly relative. Possibly 50% of the caregivers are exhausted and depressed, barely able to cope. They, too, in addition to being the gatekeeper to OTC drugs, require prescription medications and support.

A definition of an OTC: The FDA recognizes that a number of OTC drug products are used to treat symptoms of conditions that are not self-diagnosable, e.g., bronchodilators for asthma and pancreatic enzymes for pancreatic enzyme deficiency. Thus, self-diagnosis is not a necessary prerequisite to the OTC availability of drug products. A drug may be dispensed only upon prescription when "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral methods necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs."

The Benefits: Nonprescription drugs contribute importantly to patient well-being, if used intelligently and knowledgeably. Correct use can help balance the need for medical intervention against financial costs (public and personal expense). Indeed, OTC drugs are now recognized as therapeutic agents and have been defined as "appropriate for the prevention, treatment, symptomatic relief or cure of diseases, injuries, or other conditions—acute or chronic—which the consumer can identify and manage alone or with professional diagnosis or supervision."

The Risks: The hazards of drug therapy, in general, are greater in elderly patients than in younger patients, based on a myriad of patient and drug-related factors. In that sense, OTC drugs can be hazardous to the elderly. The risk is increased because these patients are often managed with multiple-drug regimens, and, in a complex regimen, OTCs can cause serious adverse reactions, additive effects, and interactions with prescription drugs. Furthermore, that risk is enhanced in the elderly, who are often sight-impaired and who may not be able to self-diagnose, select the right agents, and follow directions. Indeed, the literature reports problems with chewable tablets that were swallowed whole and had to be removed surgically, with bulk laxatives taken with insufficient fluids and the resultant need for surgical intervention, with chewable vitamin-C tablets that caused serious erosion of teeth, and with aspirin tablets placed into the oral cavity and allowed to dissolve, which caused painful burns of the mucosa.

Benefit Versus Risk: Back problems, sore throat, abdominal pain and gastrointestinal complaints, coughs, colds, constipation, and aches and pains clearly can often be managed with correct use of a properly selected OTC drug. These are frequent complaints of the elderly, who are likely to reach for an OTC product.

TABLE 1
Over-the-Counter Products Elderly Commonly Use*

| Classification | Example* |
|---|---|
| **Analgesics | |
| Headache | Acetaminophen, Aspirin, Bufferin, Excedrine |
| Arthritis | Anacin 4, Nuprin |
| **Antacids | |
| Antianxiety products | Maalox, Mylanta |
| Antidiarrheal products | Compoz, Cope, Miles Nervine |
| Antihistamines | Kaopectate, Pepto Bismol |
| Asthma products | Benadryl, Chlortrimeton |
| Bronkaid, Primatene | |
| **Cough, Cold, Allergy Products | Contac, Robitussin, nose sprays |
| Eye products | Murine, Visine |
| GI Upset, Nausea | Bonine, Dramamine, Eco, Enzymet |
| Home remedies | Sweet oil |
| **Laxatives | |
| Ointments, Creams, Powders | Chronulac, MOM |
| Otic products | Hydrocortisone |
| Personal Care products | Cerumenex, Debrox |
| | Deodorants, Depilatories, Douches, Medicated Shampoos |
| Sleep Aids | Benadryl, Sominex |
| Stimulants | Nodoz |
| **Vitamins, Minerals, Nutritional Supplements | Vitamins A, B, C, E Minerals: Calcium, Iron Potassium |
| Weight Control products | Ayds, Dexatrim |

*List of products not meant to be all-inclusive.

**Probably most commonly used

OTC Use: Statistics on OTC-drug use by the elderly are scarce (Table 1). A Canadian group reported that almost 60 percent of their study population used OTC drugs, with women using them more often than men. In another study, almost 50 percent of elderly subjects self-administered vitamins. Still another study found that almost two-thirds of elderly ambulatory patients used OTC drugs. More than half of these OTCs were oral analgesics. Cough and cold preparations accounted for 13 percent of all OTCs used. Only 12 percent of the patients using these OTCs consulted their physician about their use. In general, OTC-drug use closely parallels prescription-drug use, and many studies have documented high use of agents for gastrointestinal upset and constipation.

That use, although high, will increase. It will increase because this is the era of self-care. It will increase because more and more prescription drugs are being switched to OTC status. It will also increase because the elderly read about many new uses of nonpre-

scription products and attempt to follow what they read. They may increase their zinc intake, based on reports that zinc is said to be necessary for maintenance of vision, taste, saliva production, and olfactory senses and that the recommended daily allowance of zinc may be insufficient for them because of lessened bioavailability. They are exhorted to increase their intake of calcium in order to prevent osteoporosis, and many believe that increased calcium intake can also control hypertension. Many elderly—too many, indeed—are no longer willing to tolerate the multiple side effects of anti-hypertensive medications (often, because the side effects were not explained to them) and switch to garlic. With the introduction by a Japanese company of a colorless and odorless garlic tablet, this trend can be expected to accelerate. The elderly read about beta-carotene and use it, and they read that vitamin C is being tested as an agent potentially useful in the prevention of cancer and that vitamin A and zinc deficiencies may be associated with human esophageal carcinoma. Concerned with their health and health maintenance, they will use these and many other products. One wonders how many take aspirin in order to prevent stroke (Table II, III).

External Products: Attention is most often focused mainly on those OTC's used internally. Nevertheless, it is well to remember that many products are available for external use that are important to the elderly's well being. Among these are dry skin products, which must be used correctly. The elderly diabetic patient must protect the skin against injury, keep it clean, take care of minor cuts and bruises, and use skin softeners to treat xerosis. The elderly usually suffer more often from dry skin and its management is poorly understood by both provider and consumer. It is not just a problem to the elderly in winter, although it occurs more often then, quite often because of the drying effect of cold air, inadequate humidification of the consumer's living environment, or both.

Many dry skin products are available, including urea-containing products (elderly persons may exhibit heightened tissue-sensitivity to these), products containing vitamins A and D, and emollients. Products that are added to the bath water may make the tub slippery and dangerous for elderly persons with a lessened ability to withstand falls. Creams, although easily rubbed in and easily removed (more patient acceptance), do not occlude the skin and therefore provide little moisture to the skin. Gels, because of their alcohol content, can indeed worsen the condition. Best are the pretrolatum-based ointments, but they are hard to rub in and may therefore not find patient acceptance.

Dry eyes are a major complaint of many elderly persons. A disadvantage of products containing either methylcellulose or polyvinyl alcohol is their short duration of action, and treatment failure is often caused by lack of frequent administration. Thus, dry eyes can be treated with artificial tears, but these must be applied often.

TABLE 2
Some Products the Elderly Might Purchase in a Health Food Store

| Product | Purported activity | Possible toxicity/interaction |
|---------------|--|--|
| Ascorbic acid | Anti-aging effect, cancer & cold prevention | After high doses, abrupt withdrawal leads to scorbatic effects. False urinary sugar test result |
| Calcium | Antihypertensive Cancer Osteoporosis | Hypercalcemia (anorexia, nausea, vomiting) |
| Garlic | Antihypertensive | Defaulting with prescribed regimen |
| Herbal teas | Blood-forming, Diuretic, GI upset | Some stimulate the liver microsomal enzyme system |
| Iron | Energy, Pep | Constipation, GI upset, complexes some drugs |
| Potassium | Prevent hypokalemia | Hyperkalemia |
| Selenium | Cancer | Toxic dose and toxicity not well known |
| Vitamin E | Anti-aging effect | Interacts with some drugs, and laboratory test values. Depression (?) |
| Zinc | Cancer prevention, sexual dysfunction, wound healing | Cardiovascular effect (?) dehydration, emesis, muscular incoordination |

Health Care Products: Clearly, elderly need support with products and not just OTC drugs. Dry, forced heat can heighten the risk to respiratory problems and to dry skin. A humidifier should be recommended, but given the patient with good instructions, since both underhydration and overhydration can be dangerous to the elderly.

Patients with arthritic conditions and pain (both rheumatoid arthritis and osteoarthritis) may be advised to use a moist heat pad. However, in recommending such a product, one must be aware that elderly suffer often from "referred" pain, i.e., a bad knee may lead to pain in the hip, thus application of heat to the hip won't help. One must also be aware that the elderly do not perceive heat as well as do younger people (thus, they may tend to make the appliance too hot) and, if burned, they heal poorly and slowly.

Rx to OTC Switch: Many Rx drugs have already been switched to OTC status (Table IV) and the rate of switching is accelerating. Diphenhydramine is well known to the elderly, and, clearly, they often purchase this particular drug. But it has a not inconsequential anticholinergic effect. Added to other drugs with the same kind of side effect, it may be enough to lead to confusion, urinary retention, and even an atropine-like psychosis.

Ibuprofen products continue to be marketed. They ought to be given with caution to elderly. They may well be taking aspirin, ascorbic acid, nonsteriodals, potassium supplements and still other gastrototoxic drugs. The additional gastrototoxicity, particularly in elderly women taking a diuretic, may lead to gastric hemorrhage. Many elderly suffer from cardiovascular disease. Ibuprofen can cause sodium retention and can, therefore, aggrevate congestive heart failure. This is a time and dose-dependent phenomenon. In the very old, taking more than is recommended, even those who are not taking any other drug, it can cause the symptomatology of CHF.

TABLE 3
Foods and Plant Products as Therapeutic Agents in Folklore*

| | Suggested medicinal use |
|-----------------|---|
| Anchovies | Aphrodisiac |
| Aniseed | Digestive acid |
| Caraway seed | Digestive aid; for constipation, gout, or distemper incident to old age |
| Celery Seed | Juice is antacid and stimulant; effective for some rheumatic complaints |
| Curry powder | Purifying effect on the intestines |
| Dill seed | To soothe babies |
| Fennel seed | To restore eyesight; weight reduction |
| Juniper berries | For kidney and digestive complaints |
| Mandrake | Aphrodisiac |
| Mint | Digestive acid; for "languor following epileptic fits" |
| Mustard seed | For colds, fevers, and sciatica |
| Nutmeg | Digestive aid |
| Onion | |
| Juice | Cough and bronchitis |
| Raw | Cure for epilepsy |
| Parsley | Aphrodisiac, general tonic |
| Poppy seed | For toothache, neuralgia, and other nervous pains |
| Rosemary | Tonic and for nervous headaches |
| Saffron | For heart palpitations |
| Spinach | Aphrodisiac |
| Thyme | For headaches and nightmares |

*Adopted from Hemphill R: Spice and Savour. London, England, Angus and Robertson Ltd, 1964, and Camp J: Magic, Myth and Medicine, New York, Taplinger Publishing Company, 1974.

Currently, the FDA is considering the combination of three amino acids, i.e. glycine, alanine and glutamic acid, for use in benign prostatic hypertrophy, a fairly common condition occurring in about 50% of all men over the age of 50. While the condition is not self-diagnosable, the symptoms of the condition, i.e. urinary urgency and frequency, excessive urinating at night, and delayed urination could probably be treated by effective products.

Thus, the responsibility to the provider is clear: a good drug history is needed and must be kept updated.

Future OTC Use

Two factors are in a sort of interplay. The first one is the rising home care sector. Dr. Cluff views this largely as a provider-assisted self-care sector. Indeed, the American College of Physicians, in a recent policy statement on home care, stated that "too often, the physician is not involved in home care." Forty percent of all drugs used in nursing homes are OTC drugs, and the home care sector mirrors that use. The switch from Rx status to OTC status of many drugs is accelerating. By 1990, cimetidine will be OTC, shortly thereafter to be followed by such drugs as hydrochlorothiazide and propranolol.

TABLE 4
Prescription Drugs Reclassified as OTCs

| Drug | Indication |
|--|-----------------------------|
| Pyrantel pamoate | Pinworms |
| Diphenhydramine hydrochloride | Night time sleep aid |
| Hydrocortisone (topical) | Antipruritic |
| Hydrocortisone acetate (topical) | Antipruritic |
| Epinephrine hydrochloride | Anorectal vasoconstrictor |
| Ephedrine sulfate | Anorectal vasoconstrictor |
| Halopropin | Antifungal (except Candida) |
| Miconazole nitrate | Antifungal (except Candida) |
| Sodium-fluoride rinse | Anticaries |
| Stannous-fluoride rinse | Anticaries |
| Stannous-fluoride gel | Anticaries |
| Acidulated phosphate-fluoride rinse | Anticaries |
| Brompheniramine maleate | Antihistamine |
| Chlorpheniramine maleate | Antihistamine |
| Oxymetazoline hydrochloride (topical) | Nasal decongestant |
| Pseudoephedrine hydrochloride (oral) | Nasal decongestant |
| Pseudoephedrine sulfate (oral) | Nasal decongestant |
| Xylometazoline hydrochloride (topical) | Nasal decongestant |
| Dyclonine hydrochloride | Anesthetic/analgesic |

Specific Patients Needs

The Osteoporotic Patient: When estrogens were approved for the management of osteoporosis, the FDA required labeling that indicated that calcium should also be used. If not prescribed, it makes sense to recommend a calcium supplement. Keep in mind that a good number of elderly may suffer from hypochlorhydria or an acidity, and some calcium carbonate products would not dissolve and be absorbed. Also keep in mind that elderly are easily constipated, and calcium carbonate may act as a constipating agent.

The Cardiovascular Patient: Salt substitutes are certainly appropriate to recommend, while thought ought to be given whether ibuprofen should be recommended when the patient complains about pain. A more difficult question to answer is the question of potassium supplements. Diabetologist complain about bananas and orange juice used by every patient being placed on a thiazide diuretic, since that plays havoc with their specific

diets. The FDA has data that show that approximately 25% of elderly buy potassium supplements in health food stores, yet the recent literature seems to indicate that the danger of hyperkalemia (especially in patients receiving nonsteroidals) is greater than the danger of hypokalemia.

The Diabetic Patient: Skin care products ought to be considered, since skin breakdown is frequent in the diabetic patient.

The Arthritic Patient: If the patient is not satisfied with the analgesic effect of the nonsteroidal, careful consideration should be given as to whether to recommend an additional analgesic (most likely acetaminophen). First, clinical response to a given NSAID varies markedly among patients who appear to have the same condition. In California, according to a recent study, 69.1% of RA patients were switched from one NSAID to another, in an unpredictable pattern. RA patients had an average of 2.3 switches for six quarters. Thus, early recommendation to add another analgesic to the regimen may not permit the primary physician to evaluate the effectiveness of the nonsteroidal selected.

Some British studies have shown that on chronic use, patients receiving multiple analgesics suffer from an increased incidence of kidney dysfunction. However, one sees more and more physicians recommending the use of antacids when elderly patients are placed on nonsteroidals, in order to minimize the risk of gastrototoxicity. One might also recommend moist heat to the patient.

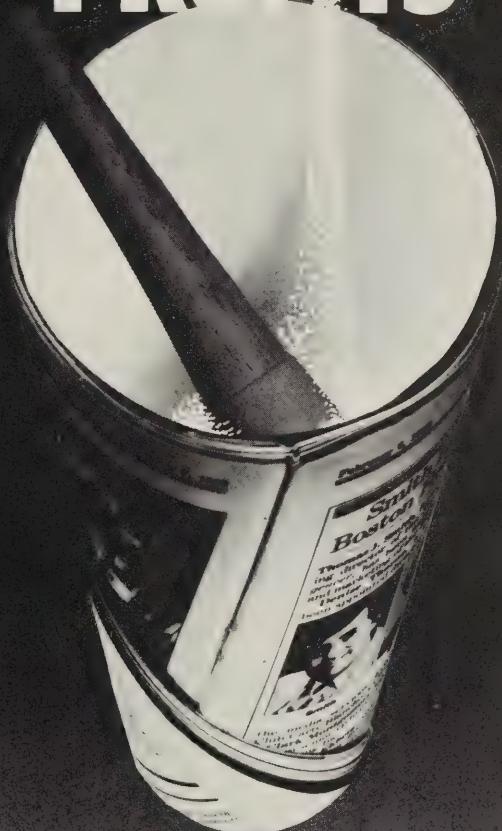
The Patient with Pain: This is a particularly difficult area. Quite often, as in arthritis, one might wish to recommend an additional analgesic once the patient has been stabilized on a specific NSAID. In other instances, it might be better to recommend against a specific analgesic. For example, if an elderly patient already is receiving medication that might adversely impact on the thermoregulatory mechanism (functioning less efficiently with advancing age), then aspirin would not be the analgesic of choice (it can help lead to hypothermia). If an elderly patient already suffers from ringing in the ears, aspirin would not be the first choice, since tinnitus is a sign of aspirin toxicity.

Economic considerations must enter into these considerations. One of the new OTC ibuprofen products is targeted for "musculoskeletal conditions and minor pain of arthritis", when, indeed, the side panel of the package also lists "headache". Thus, it would be unnecessary and economically disadvantageous for the elderly patient to purchase the product for headache, and one for minor musculoskeletal pain.

Continued on page 14.

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly and Chairman, Department of Pharmacy Practice and Administrative Science, School of Pharmacy and Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, Maryland 21201

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The Patient with GI Complaints: The majority of elderly admitted to a hospital have a primary or secondary diagnosis the complaint of GI "upset". One must remember, though, that 30% of all GI complaints in the elderly are behaviorally-induced, and not age- or disease-related. In any case, elderly, particularly elderly women, are more susceptible to GI side effects than are younger adults, and often, an antacid is indicated for drugs known to be able to cause GI complaints.

The Chronic Care Patient: It has long been known that use of some chronic drugs can lead to deficits in specific nutrients. Coupled with the often demonstrated deficit of many vitamins in the elderly, it is not unreasonable to recommend vitamin use. Table V lists those drugs where vitamin supplementation may well be indicated. It also lists those prescription drugs whose action might be negated if certain vitamins are taken by the patient.

TABLE 5
Chronic Drug Therapy and Vitamins/Minerals

| Drug | Recommendation |
|-------------------------|--|
| Antacids | Supplement folic acid |
| Aspirin | Supplement ascorbic acid, folic acid, iron |
| Chlortetracycline | Supplement riboflavin, ascorbic acid, calcium |
| Cholestyramine | Supplement vitamins A, D, and K, folic acid |
| Colestipol | Supplement vitamins A, D, and K, folic acid |
| Coumarin anticoagulants | Avoid vitamin K |
| Estrogen/progestin | Supplement vitamin B ₆ , folic acid; avoid vitamin C (high doses) |
| Hydralazine | Supplement vitamin B ₆ |
| Indomethacin | Supplement iron |
| Isoniazid | Supplement vitamin B ₆ , niacin, vitamin D |
| Isotretinoin | Avoid vitamin A |
| Levodopa | Restrict vitamin B ₆ |
| Mineral oil | Supplement vitamins A and D |
| Penicillamine | Supplement vitamins B ₆ |
| Phenothiazines | Supplement riboflavin |
| Phenytoin | Supplement folic acid (but limit to 1.0 mg/day) |
| Primidone | Supplement vitamin K |
| Rifampin-isoniazid | Supplement vitamin B ₆ , niacin, vitamin D |
| Sulfasalazine | Supplement folic acid |
| Tetracycline | Supplement riboflavin, ascorbic acid, calcium |
| Triamterene | Supplement folic acid |

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Institutional Forum

Review of 1984-1986 Hospital Pharmacy Operations

James R. Talley, M.S.
Northeast Louisiana University

Lilly Survey

This review of 1984-1986 hospital pharmacy operations was abstracted from editions of the *Lilly Hospital Pharmacy Survey*. Table 1 lists summary information for the years 1984-1986. The average hospital has had a reduction of 4.1% beds (10 beds) from 1984 with a census decrease of 4%. The average census has been falling consistently since 1982 and is approximately 14% less than the 73% average rate observed from 1975-1981.

The average length of patient stay continued to decline from previous years to 6.0 days in 1986 which represented a 9.1% decrease since 1984. Although the

number of hours the central pharmacy was open slightly declined in 1986, the figure is constant with the 1984 figure of 97 hours. The hours worked by pharmacists, technicians, and support personnel have slightly increased since 1984 (+1.4%, +3.1%, & +5.5%).

For the third year, total inventory showed a slight decrease (-.07%). However, inventory based on per patient day, per bed, per occupied bed, and per admission all increased (+4.8%, +3.0%, +4.8%, & +1.1%). It is interesting to note that purchases increased for all of these categories (+7.7%, +5.9%, +7.7%, & +3.8%). Once again the inventory turnover rate increased and was 8.7 in 1986 compared to 7.8 in 1984.

TABLE 1
Average Hospital pharmacy (general private nonprofit)

| | 1984 | 1985 | 1986 | Change 1984-85 | Change 1985-86 | Change 1984-86 |
|--|------------|------------|------------|-------------------|-------------------|-------------------|
| Bed capacity | 245 | 244 | 235 | -4% | -3.8% | -4.1% |
| Census (occupied beds) | 63% | 60% | 59% | -3% | -1% | -4% |
| Admissions | 8582 | 8566 | 8416 | -0.2% | -1.8% | -1.9% |
| Patient days | 56338 | 53436 | 50607 | -5.2% | -5.3% | -10.2% |
| Length of patient stay (days) | 6.6 | 6.2 | 6.0 | -6.1% | -3.2% | -9.1% |
| Hours central pharmacy open/week | 97 | 100 | 97 | +3.1% | -3.1% | 0% |
| Pharmacist hours/week (FTE) | 290 7.3 | 309 7.7 | 294 7.3 | +6.6% | -5.1% | +1.4% |
| Technician hours/week (FTE) | 260 6.5 | 276 6.9 | 268 6.7 | +6.2% | -3.0% | +3.1% |
| Support personnel hours/week (FTE) | 109 2.7 | 114 2.9 | 115 2.9 | +4.6% | +0.9% | +5.5% |
| Inventory | \$121414 | \$121198 | \$120397 | -0.2% | -0.7% | -0.8% |
| /patient day | \$2.16 | \$2.27 | \$2.38 | +5.1% | +4.8% | +10.2% |
| /bed | \$498 | \$497 | \$512 | -0.2% | +3.0% | +2.8% |
| /occupied bed | \$786 | \$828 | \$868 | +5.4% | +4.8% | +10.4% |
| /admission | \$14.15 | \$14.15 | \$14.31 | 0% | +1.1% | +1.1% |
| Purchases | \$944569 | \$1032831 | \$1053736 | +9.4% | +2.0% | +11.6% |
| /patient day | \$16.77 | \$19.33 | \$20.82 | +15.3% | +7.7% | +24.2% |
| /bed | \$3855 | \$4233 | \$4484 | +9.8% | +5.9% | +16.3% |
| /occupied bed | \$6118 | \$7055 | \$7600 | +15.3% | +7.7% | +24.2% |
| /admission | \$100.06 | \$120.57 | \$125.21 | +9.6% | +3.8% | +13.8% |
| Inventory turnover rate | 7.8 | 8.5 | 8.7 | +9.0% | +2.4% | +11.5% |
| Floor area central pharmacy (square feet) | 1734 | 1799 | 1712 | | | |

The ranking of services provided by pharmacy departments was the same in 1986 as in 1985 (Table 2). However, in 1985 these services were offered by over 70% of pharmacies compared to 1986 where they were offered by over 60% of pharmacies.

TABLE 2
Services offered by Pharmacies

| | 1986 | 1985 |
|-------------------------------------|-------|--------|
| % pharmacies offering services | >60% | >70% |
| Monitoring patient profiles | 94.4% | 96.5% |
| Monitoring drug interactions | 91.2% | 92.6% |
| Providing drug information services | 74.6% | 82.5% |
| Drug therapy consultation | 67.9% | 71.25% |

Effects of Cost Containment

Current cost-containment for health care was initiated by the implementation of Medicare prospective pricing in 1984. The pressure continues for hospitals to further reduce costs and be more efficient in treating patients. The results are that length of patient stays have declined whereas the intensity of care has increased. Thus, the average hospital occupancy rate, the number of patient days, and hospital admissions have decreased.

In 1985, peer review organizations (PROs) were implemented which focused on unnecessary Medicare hospital use. These aspects of cost containment for Medicare patients created similar pressure for cost containment in the private sector of health care. It is possible that private use-review programs may have an even more profound effect than Medicare prospective pricing and PROs on hospital admissions, patient days, and average occupancy.

A number of insurance companies and employers are promoting the concept of private use-review programs. These programs include preadmission review, second-surgical-opinions, continued-stay review, and case-management services. Companies engaged in preadmission and concurrent review are predicting reductions of 15% to 20% for the number of hospital patient days.

These factors are resulting in a decreased use of hospital inpatient services. One report stated that in 1985, hospital out-patient visits increased by 4.7%, in-patient admissions decreased by 4.4%, and average hospital occupancy attained a new low of 64%. This decrease in the use of hospital in-patient services has resulted in a decline of revenue for hospitals. In an attempt to off-set this decline in revenue, hospitals are engaging in alternative-care (home-care) services and for-profit subsidiary corporations. These include home infusion therapy programs, durable medical equipment, and joint ventures with physicians.

This decrease in the length of patient stay has resulted in an increase in the intensity of care provided patients. These aspects are directly affecting pharmacy services in hospitals because aggressive drug therapy is resulting in an increase use of injectable dosage forms. The increased costs of using parenteral products results in a disproportionate increase in costs for pharmacy services. Unfortunately, hospital administrators may exert even greater pressure on pharmacy managers to obtain a proportionate decrease in pharmacy expenses as compared to other departments. A task which may be almost impossible. Thus, hospital pharmacy managers are being forced to reevaluate pharmacy services. This reevaluation may equate to a decrease in pharmacy services to patients.

Conclusion

The pressure on pharmacy to reduce costs is tremendous. Hopefully, the pharmacy profession will create innovative cost-reduction programs which will not sacrifice patient care. Our goal must remain, "to deliver the highest level of patient care at the least possible costs."

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JCPP Reaffirms Support of Uniform Expiration Dating

In 1981, the Joint Commission of Pharmacy Practitioners (JCPP) endorsed the concept of a uniform semi-annual expiration dating policy for all prescription drugs with a shelf life of at least 36 months. Suggested expiration dates were January and July.

The Commission contacted seventy (70) pharmaceutical manufacturers during 1981 to determine their current expiration date policies and if the firms would consider adopting the policy supported by members of the Commission. Based upon a series of letters and meetings with executives of the companies, thirteen manufacturers reported that they would review current policies with the expressed hope that they would be able to assist practitioners with this important matter. In addition, eight manufacturers had adopted six month expiration dating on most of their products (in accordance with the position statement adopted by JCPP members).

In April of 1987, the JCPP reaffirmed its members' position on this important issue. The Commission contacted fifty-four (54) pharmaceutical manufacturers and expressed their support of voluntary compliance with semi-annual dating and labeling policies. Those pharmaceutical manufacturers without semi-annual dating were encouraged to adopt the recommended policies.

Thirty-two (32) of the manufacturers contacted did not provide a response to the policy recommendation. Of the twenty-two who did reply, six (6) reported that current policies would be reviewed to determine the feasibility of semi-annual expiration dating. Thirteen (13) manufacturers indicated that they would not support a uniform semi-annual expiration dating policy.

In the 1981 survey A. H. Robins Company, Merrell Dow, Parke Davis/Warner Lambert, Riker Laboratories, Sandoz, E. R. Squibb & Sons and Wyeth indicated existing use of semi-annual expiration dating. In the 1987 survey A. H. Robins Company reported that the recommended semi-annual dating policy had been in place for a number of years utilizing the January and July dates as suggested by the Commission. Boehringer Ingelheim Pharmaceuticals, after evaluation of the JCPP recommendation, indicated that it will establish January/July expiration dating for all products that have a shelf life of 36 or more months as of January 1988. The Upjohn Company has indicated that senior management has approved the requested expiration dating policy, and it will be implemented in the near future.

The Joint Commission of Pharmacy Practitioners commends those manufacturers for use of semi-annual expiration dating policies. Such a policy will assist pharmacists' efforts to control inventory levels and ensure that patients' medications are dispensed or returned prior to the expiration date approved by the Food and Drug Administration.

Expiration Dating Policies of Select Pharmaceutical Manufacturers

| Manufacturers | Use six mo. dating | Will review | No support | No response |
|----------------------------|--------------------|-------------|------------|-------------|
| Abbott | | | '81/'87 | |
| Allergan | | '81 | '87 | |
| Astra | | | '81 | '87 |
| Ayerst | | '81 | | '87 |
| Beecham | | | '81 | '87 |
| Berlex | | | '87 | |
| Boehringer Ingelheim | '87 | | | |
| Bristol Labs | | | '81 | '87 |
| Burroughs Wellcome | | | '81/'87 | |
| Carter-Wallace | | | '81 | '87 |
| *Ciba-Geigy | | | '81/'87 | |
| Coopervision | | | '81 | '87 |
| Hoechst-Roussel | | '87 | '81 | |
| Knoll | | | '81 | '87 |
| Lederle | | | '81 | '87 |
| Eli Lilly | | | '81/'87 | |
| Merck Sharp & Dohme | | | '81/'87 | |
| Merrell Dow | '81 | | | '87 |
| Miles | | | | '81/'87 |
| Mylan | | | '87 | |
| Norwich-Eaton | | '81 | '87 | |
| Parke-Davis/Warner Lambert | '81 | '87 | | |
| Pfizer | | | '81/'87 | |
| Riker Labs | '81 | | | '87 |
| A. H. Robins | '81/'87 | | | |
| Roche Labs | | '81 | '87 | |
| William H. Rorer | | '87 | '81 | |
| Ross Labs | | | '81 | '87 |
| Sandoz | '81 | | | '87 |
| Schering | | | '81/'87 | |
| Searle | | '81 | | '87 |
| **Smith Kline & French | | | '81/'87 | |
| E. R. Squibb & Sons | '81 | | | '87 |
| Stuart | | | '87 | |
| *Syntex | | '87 | | |
| The Upjohn Company | '87 | | '81 | |
| Westwood | | | '81 | '87 |
| Wyeth | '81 | | '87 | |

* Ciba-Geigy and Syntex have had a semiannual dating policy in place in the past. Both companies have now discontinued the policy.

** Smith Kline & French has a semiannual dating policy in place for drugs with shelf life of >60 months.

Nuclear Pharmacy Exam Set for April 8, Anaheim

The Board of Pharmaceutical Specialties (BPS) has scheduled the 1989 Nuclear Pharmacy Certification Examination (NUSPEX) for Saturday, April 8, 1989, in Anaheim, CA. An additional site and date may be scheduled if deemed necessary.

Nuclear pharmacists interested in taking this examination should contact Samuel H. Kalman, Secretary, BPS, 2215 Constitution Ave., NW, Washington, DC 20037; (202) 429-7534.

BPS was established on January 5, 1976. After 3 years of study, the APhA Task Force on Specialties in Pharmacy recommended the establishment of a board through which practice specialties could be recognized. BPS is composed of nine members—six pharmacists and three non-pharmacists (one public representative and two practitioners from other health professions.)

Nuclear pharmacy has been a recognized specialty since 1978. The first Nuclear Pharmacy certification Examination was given in 1982. Currently, there are 112 board-certified nuclear pharmacists in the United States.



Pharmacy Video Features Three From UMAB/UMMS

Dr. David S. Roffman, Dr. David A. Meyerson and Lonnie J. Rogers, R.N., are the leading actors in a new video recently filmed at UMAB/UMMS under the auspices of the Eli Lilly Company. To be distributed free as a service to hospital pharmacists throughout the nation, the 20-minute tape follows a patient with a myocardial infarction from the time he arrives at the hospital until he is discharged. Emphasizing the medications used in his treatment, the presentation is accompanied by a monograph that suggests study questions for pharmacists who will be using the tape for continuing education.

Dr. David Roffman, who appears most frequently before the camera, has recently been named vice-chairman of the School of Pharmacy's clinical pharmacy department and is a research assistant professor in the School of Medicine's department of cardiology. Additionally, he is therapeutic consultant at the CCU and was chosen for his spokesperson role on the recommendation of his peers here and elsewhere, said Jerome Tovo, the film's writer-producer. Tovo added that UMMS/UMAB's "team approach" to patient care was a significant factor in the choice of this campus as the location for the shoot.

Dr. Meyerson is director of coronary care and telemetry units and director of preventive cardiology programs in the School of Medicine and Lonnie Rogers, formerly the unit-based educator for the CCU, is a nurse recruiter for UMMS.

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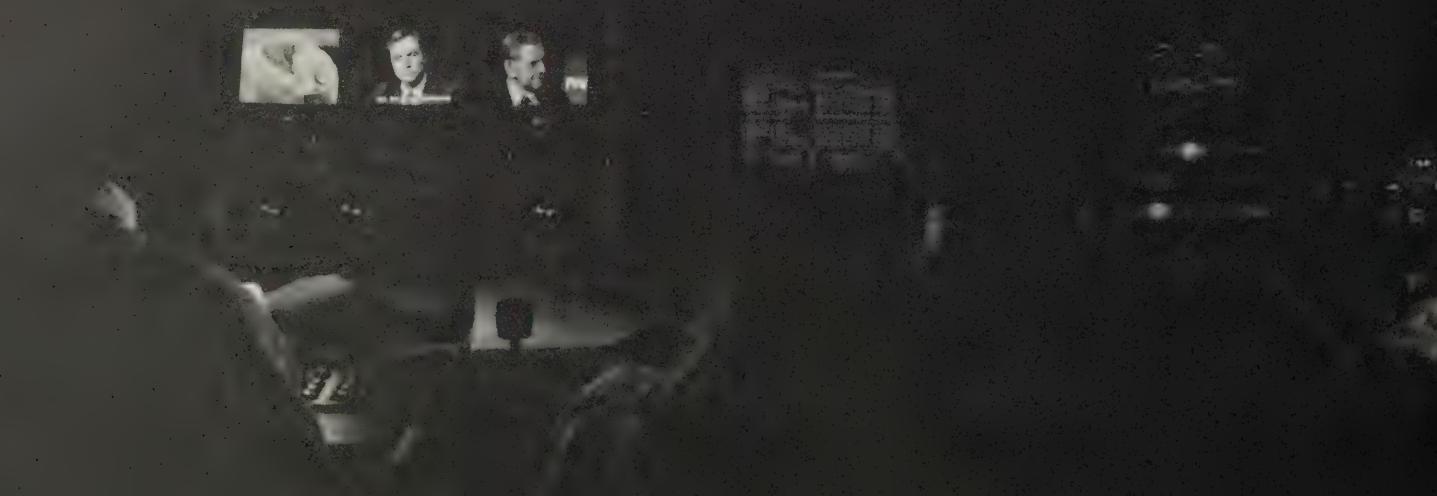
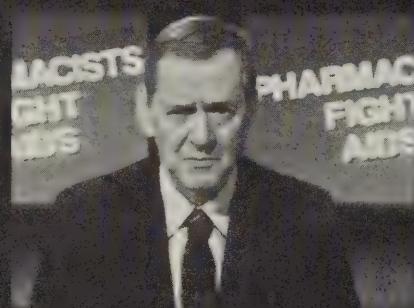
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National Forum

Open Letter to Employers

(Copy onto your own letterhead or use as a model in composing your own letter.)

Dear Employer:

"An estimated 125,000 Americans die each year from failure to take their medicine as prescribed." With this single statistic, a leading pharmacy publication, *American Druggist*, sums up both the important role of pharmaceutical products in our country and the dangers when patients lack the information they need about their prescription medicines.

The survey of 2,000 randomly-selected adults, in the July 1987 issue, also showed that:

- 7% of patients do not have their prescription orders dispensed;
- 15% of patients do not take their prescription medication for the full length of time;
- 32% of patients do not have their prescription orders renewed, even though they need to do so;
- 43% want more information on the medication itself, including data on side effects;
- 19% want more information on dosage and how it should be taken.

The April 1987 issue of *Business and Health* notes some disturbing statistics: "Up to 50% of the 1.6 billion prescription orders dispensed annually are being taken incorrectly by the patient, resulting in a loss of \$13 billion to \$15 billion in health care, 125,000 deaths and several hundred thousand hospitalizations. . . . One of every four prescription orders written is for a person 65 years of age or older, who, on the average, receives approximately 13 prescription drugs a year."

It is clear that the use of drugs is a major aspect of health care. The consequences of drug use or misuse have far-reaching and widely-variable effects on both the quality of life and the general economic climate. Appropriate education, monitoring, and utilization review can be expected not only to increase general well-being, but to save millions of dollars and reclaim many lost man-hours of productivity.

Pharmacists are the most available health professionals to accomplish these needed improvements. The pharmacist is often the first health professional contacted by a person, and is the health professional most often visited. The pharmacist has great opportunity to assess and monitor drug therapy. By education and training, pharmacists are the most knowledgeable health practitioners regarding drug use and effects. An employee's family pharmacist is available to monitor for drug interactions and adverse effects, consult on nonprescription drug usage, perform triage, and perhaps most importantly, provide immediate feedback to the physician when warranted.

The face-to-face consultation that is possible only between an employee and his or her family pharmacist often provides vital information about the patient's understanding of the pharmacist's or physician's instructions regarding the proper use of medication. The pharmacist interacts with the employee on many levels, both professionally and as a member of the same community, an irreplaceable community resource who should not be discounted.

When your benefits administrator budgets for pharmacist services, both dispensing and monitoring/education, as a separate or combined service, he or she is investing in the health and quality of life of your employees. That means investing in the well-being of your business. The return on investment in economic and health terms is attractive and this asset belongs in every company's portfolio.

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Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer. In most patients, the ulcer will heal within four weeks.

Axid is indicated for maintenance therapy for duodenal ulcer patients, at a reduced dosage of 150 mg b.i.d. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known.

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H₂-receptor antagonists.

Precuations: General—1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy.

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests—False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine.

Drug Interactions—No interactions have been observed between Axid and theophylline, chlorazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect.

There was a dose related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice,

although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups.

The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement

compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, prenatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect, but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates. Although no studies have been conducted in lactating women, nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established.

Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups.

Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to

determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 U/L), and in a single instance, SGPT was greater than 2,000 U/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antidiuretic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H₂-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported.

Overdosage: There is little clinical experience with overdosage of Axid in humans. If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

Treatment animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous LD₅₀ values in the rat and mouse were 301 mg/kg and 232 mg/kg respectively.

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Dickinson's Pharmacy

by Jim Dickinson

A golden opportunity lost. "First and foremost, it seems to me that this brief should be viewed not as an adversarial endeavor but as a golden opportunity for the Pharmacy Association to have significant input in defining the role and responsibility of pharmacists in this state's health care system."

So wrote Washington State attorney Stephen J. Franks, in a scholarly memorandum of law for the state association to consider in preparing an amicus brief for the state Supreme Court, which has been reviewing a landmark "duty to warn" case involving two pharmacists and an injured patient.

It isn't every day—or even every half-century—that a pharmaceutical association anywhere in the world is asked to help a supreme court make new law for the profession.

A golden opportunity, indeed. But, for diverse and hidden reasons, in an era of the mail-order avalanche and dispensing physicians, this one seems to have turned into an opportunity lost.

The essence of the case bothering the Washington Supreme Court is almost incidental to the historic opportunity that pharmacy had.

But since the facts constitute the doorway surrounding the opportunity, let's quickly review them. For 10 years, pursuant always to a valid prescription and to state law, Elaine McKee kept taking Plegine (anorexiant phendimetrazine tartrate), a drug that carries dependency and two-week tolerance warnings, in addition to other unpleasant side-effects. McKee unsuccessfully sued Seward Park Pharmacy for failing to warn, and took it to the Supreme Court, which apparently felt it wanted to consider whether pharmacists should counsel their patients more than they now do. It asked the state association for help.

The state association asked Franks' law firm, Short, Cressman and Burgess to prepare an *amicus curiae* (friend of the court) brief. But, somewhere between Franks' positive April 20 memo to his principal and the Supreme Court itself on the May 5 filing deadline, the *amicus* brief chickened out, arguing on the side of Seward Park Pharmacy that there is no duty to warn.

It sided with the oppressive, long history of past cases that say, in essence, that the pharmacist is a store clerk moving dangerous merchandise. It turned its back on a small but growing body of new law which holds

that pharmacists have risk management responsibilities as the agents of their patients.

Pharmacists, as a whole, don't rush to embrace new and open-ended liabilities. That's why the old law has stayed around as long as it has. But the climate of professional opinion has been undergoing radical change for almost a decade now, and its pace has been quickened by the onslaught of mail-order and dispensing physicians—not to mention the rise of a more sophisticated patient.

What happened to the golden opportunity extended to the profession in Washington?

The state association is in uproar, but a deadline is a deadline and an *amicus* brief once filed can't be recalled. University of Washington Pharmacy Administration Professor Bill Fassett, who has been following the controversy as it unfolded, suspects that the pressure of the deadline caused the association's executive committee to refrain from referring the Supreme Court's question to wider professional discussion.

Had it done so, the profession's contrary opinion, as evidenced in the ensuing uproar at the annual convention in June, would have been foreseen. As it was, the convention was presented with a *fait accompli*, and there was nothing left to do but fume.

Perhaps even by the time this column is read, the Washington State Supreme Court will have issued an opinion that turns the clock back (because, until now, Washington had seen a "bellwether" state in its promulgation of the most sweeping pharmacy counseling regulation in the country).

In an excellent overview of the mandatory counseling issue in the July 4 issue of *Drug Topics*, it was revealed that a dozen states already require or are considering requiring patient counseling. Except for Washington, the requirement is usually perfunctory—limited to directions for use, and any notorious warnings, such as alcohol interactions.

Washington's 21st-century regulation provides for the dispensing of utilization information as well as for the monitoring of drug therapy, which includes the collection and use of the patient's drug history, the measurement of vital signs, the ordering and evaluating of the results of laboratory tests.

Looking at these expansive and rather frightening rules, the association's *amicus* brief begged the Supreme Court to accept that the monitoring requirements could obviously apply only to the institutional practice of pharmacy—a limitation that is not obvious in the reading of the regulation.

This feature is presented on the grant from G.D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

The Supreme Court asked the association: "Does a community pharmacist who is authorized by the patient's physician to refill a lawful prescription, have a duty independently to evaluate the physician's continuing course of drug therapy and consult with either the patient or the physician for the purpose of advising the patient to stop taking the drug?"

The association's hurried lawyers' brief answered, on the basis of long-established law: "Pharmacists do not have a duty independently to evaluate a physician's choices and course of prescription drug therapy."

In discussing the most important recent case compelling a duty to warn (*Riff v. Morgan*, cited by litigant McKee), the association's brief heavily downplayed the court's comment that pharmacists have a limited duty to be their brother physician's keeper, and instead cast the case in the narrowest possible terms. The emphasis should be on the word "limited."

Riff, it said, "simply recognizes that a pharmacist should not fill a prescription containing a lethal or potentially lethal dosage."

That standard is, of course, little more than the state would apply to a bartender selling liquor to a paralytic drunk who later died.

Listening to the lawyers and the learned judges debating the possibly stillborn new world of pharmacy during oral argument on the case, Washington State Pharmaceutical Association executive Raymond A. Olson could barely contain himself. His written observations record that ". . . it was most frustrating to sit and listen to attorneys on both sides of the table talk about pharmacy without knowing much about the profession."

Instead of providing such a sweeping, unilateral "No" to the Supreme Court's question about the pharmacist's duty, most Washington state pharmacists and interested colleagues across the country no doubt would have preferred a qualified "Yes." After all, this was a golden opportunity to give the profession something more important to do than putting prescriptions into the mail.

EMPLOYEE/EMPLOYER RELATIONS FORUM DUDLEY DEMAREST, P.D.



As I stated in our first column, "pharmacists don't seem to have the need, desire, or maybe just the time to converse with their fellow practitioners." Well things are changing. The University of Maryland School of Pharmacy recently announced the development of a computer conferencing system for Maryland pharmacists. The project, under the direction of Dr. Alan B. McKay, is funded by a grant from the Merck Foundation.

The conferencing system will initially involve Professional Experience Program (PEP) preceptors in the Baltimore-Washington corridor who have computers at their place of business or at home. Pharmacists who do not own a modem are being provided one, together with communications software. The conferencing system is called CoSy, and was developed at the University of Guelph in Canada. The system is already in widespread use on the Baltimore Campus.

CoSy already offers many "conferences" on line to the campus community. Conferences topics range from research in progress to topics of general interest. Included are: best buys in software and hardware, computer graphics, gardening, AIDS research, restaurant reviews, jokes, databases, Artificial Intelligence research, . . .

Anyone can start a conference on any subject at all; the university supplies handbooks and manuals on how to start your own. Several committee members are already planning practice oriented conferences.

If all goes well Dr. McKay hopes to expand the system to include pharmacists from across the state as well as non-preceptors. Any pharmacist with a modem and communications software will be able to access the computer conferencing system.

If you're interested in getting on line with other pharmacists give the EMPLOYEE/EMPLOYER RELATIONS committee a call at the Kelly Building. We'll relay your requests to Dr. McKay. Hopefully a good response will allow him to expand the system.

MPhA Mid-Year
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**PHARMACY ACHIEVEMENT SCHOLARSHIP
UNIVERSITY OF MARYLAND
School of Pharmacy**

The University of Maryland School of Pharmacy's Annual Pharmacy Achievement Scholarship represents an exciting challenge to you as a practitioner concerned with the future of our profession. By sponsoring a qualified high school or college student (Maryland Resident) for this tuition-free one-year scholarship, you will:

- 1) stimulate general community interest in the profession;
- 2) encourage one outstanding young person of your acquaintance to choose pharmacy as a career;
- 3) demonstrate to your colleagues an awareness of the need for more and better pharmacy students.

The guidelines are simple. The student that your sponsor must have a satisfactory record of achievement in high school or college, an interest in pharmacy as a career, a cumulative grade point average of 2.75 or equivalent, and PSAT/SAT scores ready

for submission. He or she then completes the Student Section of the form enclosed, while you complete the Pharmacist's Section. You then *mail both forms*—to be received no later than midnight December 15th—to:

The Pharmacy Achievement Scholarship Committee
University of Maryland—School of Pharmacy
20 North Pine Street
Baltimore, Maryland 21201

That's all there is to it.

The recipient will be selected by representatives of the School of Pharmacy, the Maryland Pharmaceutical Association, the Alumni Association, the Maryland Pharmaceutical Society and the Maryland Society of Hospital Pharmacists. The award (one year's tuition) will be announced at a formal ceremony for all nominees and sponsors at the School of Pharmacy during the Spring term. The recipient will be required to meet established admission requirements for the School of Pharmacy at the time of entry.

For additional forms or further information, call Dr. Grady Dale, Director of Student Affairs, 328-7650/328-6586.

**UNIVERSITY OF MARYLAND
PHARMACY ACHIEVEMENT SCHOLARSHIP**

PHARMACIST'S SECTION

I nominate _____ for the School of Pharmacy Annual Pharmacy Achievement Scholarship.

Pharmacist's Name: _____

Address: _____

Name of Pharmacy: _____

College of Pharmacy: _____ Degree _____

Year _____

Telephone # _____

Indicate below why you feel this student is deserving of this scholarship. Include how you came to know the student and his/her qualities and attributes. Also include your knowledge of his/her extracurricular activities and how the student has demonstrated an interest in pharmacy as a career.

**APPLICATION
(Please type or print)**

**Note: All writing must be kept within the space provided. No additional information may be attached. To do so may void the application.

Please make sure the student you have nominated has completed all the information on the other side of this application before sending to the Scholarship Committee.

Sponsoring Pharmacist's Signature

Date

Send completed form to:

Pharmacy Achievement Scholarship Committee
University of Maryland-School of Pharmacy
Baltimore, Maryland 21201

STUDENT SECTION

Date of Application _____

Name: _____ Telephone # _____

Address: _____

Permanent Address (if different from above) _____

List your most recent place(s) of employment (if any):

| <u>Employer</u> | <u>Dates of Employment</u> | <u>Brief Description of Duties</u> |
|-----------------|----------------------------|------------------------------------|
| 1. | | |
| 2. | | |

Indicate any extracurricular (social or service) activities.**

Briefly, how did you become interested in pharmacy as a career?**

Describe how you came to know the pharmacist nominating you for this scholarship.**

Include transcript of high school grades (college transcript if beyond first year of college). PSAT, SAT and/or ACT scores must be submitted if not included on transcript. NOTE: The awarding of the scholarship does not constitute admission to the School of Pharmacy. The recipient must be a bona fide full-time student at the University of Maryland School of Pharmacy in order for the scholarship to be activated.

Student's Signature

Note: DO NOT WRITE OUTSIDE of the box or attach additional information. To do so may void the application. THIS APPLICATION MUST BE RECEIVED NO LATER THAN DECEMBER 15TH.



Lance Berkowitz, owner of Arcade Pharmacy has been appointed to the State Board for Community Colleges.



Brian Sanderoff received the 1988 Outstanding Young Maryland Pharmacist Award from Marion Laboratories at convention.



Gary Magnus and Beverly Yachmetz were honored at the convention for reactivating the Prince George's/Montgomery County Association.



Outgoing Chairman Feinberg presented Incoming President Alpern with the NARD Leadership Award.

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In Washington, 937-5300
In Baltimore, 1-800-492-1054**

Meet the Roche Community Pharmacy Advisory Board



Roche Laboratories



a division of Hoffmann-La Roche Inc.

They come from across the country to represent you and pharmacy on the Roche Community Pharmacy Advisory Board.

Input from pharmacists and our Advisory Board members helps Roche respond to your needs. This ongoing dialogue allows Roche to maintain responsible pharmacy-oriented marketing and business policies that set the standard for the industry.

Yosh Inahara, R.Ph.
Seaton Pharmacy
Portland, OR.

N. Bruce Bettencourt, R.Ph.
Village Pharmacy
Scotts Valley, CA.

Jerry Klimetz, R.Ph.
Medical Arts Pharmacy
Ft. Lauderdale, FL.

Charles Monahan, Jr., R.Ph.
Monahan Pharmacy, Inc.
Worcester, MA.

George Chapman, R.Ph.
Lamar's Drugs
Vidalia, GA.

Patricia T. Kopec, R.Ph.
Buchanan Pharmacy
Peekskill, NY.

Robert Roth, R.Ph.
Parkway Pharmacy
Beachwood, OH.

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Hopkins Pharmacy
Houston, TX.

Nicholas Lykos, R.Ph.
Lykos Pharmacy
Timonium, MD.

Robert Schwartz, R.Ph.
Schwartz Pharmacy
Milwaukee, WI.

The Advantages of Professional Portfolio Management

by

Gerald I. Klein

Consulting Group Associate
Shearson Lehman Hutton
36 S. Charles St., Suite 2201
Baltimore, Md. 21201

Have you suddenly received a large lump-sum from your employer such as an early-retirement bonus?

Have you inherited a significant sum recently?

Have you sold your business or an expensive piece of real estate?

Or have you simply begun to realize that you can no longer devote the time and attention to your investments that they require?

If you answered "yes" to any of these questions, you should consider turning your portfolio over to a professional investment advisory firm (also called a money management firm). A good investment adviser strives to produce an above-average return on your money by selecting securities to meet your specific goals and needs, monitoring the portfolio's performance and changing the mix of securities when necessary.

You may think that such professional, *personalized* investment management is for "other" people—those who are much wealthier than you. *Not so.* The minimum amount needed to obtain investment advisory services has dropped far below the half-million or million dollars required just a few years ago.

Today some respected managers accept accounts of \$50,000 and less. However, these smaller amounts usually must be in the form of IRA or Keogh accounts. Annual fees for the service range from about 3% of the value of your portfolio for smaller accounts to 0.5% for seven-figure accounts.

More than 10,000 investments advisers are currently registered with the Securities & Exchange Commission—which makes finding the right one daunting. If you've been investing through a Financial Consultant at a full-service brokerage firm, he or she can probably provide you with a list of advisers the firm has worked with successfully.

If you're wondering why your Financial Consultant would recommend an investment adviser, the answer is simple: An adviser does not compete with your Financial Consultant but works *with* him or her to provide you with the best investment management possible.

Some investment advisers operate independently, while others may be affiliates of brokerage firms. If you are considering the services of an adviser, you should talk with your Financial Consultant. The reason is that advisers have different minimums and pursue different investment strategies. So it is up to you and your Financial Consultant to find one that matches your needs.

For example, under the Shearson Lehman Hutton umbrella alone there are several independent investment advisory groups, each geared to a different group of investors. You may choose portfolio management geared to stocks only, various mixes of stocks and bonds, municipal bonds, convertible securities, even futures. If you have \$50,000 or more in cash securities, for example, and your primary goal is long-term capital appreciation, you can tap the experts at Shearson Equity Management. Or, if you have at least \$100,000 to invest and seek the highest practical return with low risk, you can have your portfolio handled by Shearson Asset Management or Hutton Investment Management.

When considering any advisory firm, make sure you understand clearly how it calculates performance data, as there is no industry standard for reporting results. Look closely at its performance figures in down markets especially and over long periods (say, 10 years). Be sure to compare the records of several firms with similar objectives.

Once you place your funds with a money management firm, review the results quarterly. Stick with a manager, though, for at least one year. Short-term ups and downs in the market make it impractical and unrealistic to jump to conclusions based on quarterly performance.

Shearson Lehman Hutton investment advisors and their plans have been endorsed by MPhA as a membership benefit. Contact the MPhA office for more information.



A REVOLUTIONARY ORAL ANTIMICROBIAL WITH THE POWER OF PARENTERALS

- Highly active *in vitro* against a broad range of gram-positive and gram-negative pathogens, including methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa**
- For treatment of infections in the:
 - lower respiratory tract[†]
 - skin/skin structure[†]
 - urinary tract[†]
 - bones and joints[†]
- Convenient B.I.D. dosage – 250 mg, 500 mg and 750 mg tablets

**In vitro* activity does not necessarily imply a correlation with *in vivo* results.

[†]Due to susceptible strains of indicated pathogens. See indicated organisms in Brief Summary.

CIPRO® SHOULD NOT BE USED IN CHILDREN OR PREGNANT WOMEN.

A history of hypersensitivity to ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin.



Miles Inc.
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Please see adjacent page of this advertisement for Brief Summary of Prescribing Information.



**■ 500 mg B.I.D. for most infections;
750 mg B.I.D. for severe or complicated infections.**

BRIEF SUMMARY

CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Cipro® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Lower Respiratory Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, and *Streptococcus pneumoniae*.

Skin and Skin Structure Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* (penicillinase and nonpenicillinase-producing strains), *Staphylococcus epidermidis*, and *Streptococcus pyogenes*.

Bone and Joint Infections caused by *Enterobacter cloacae*, *Serratia marcescens*, and *Pseudomonas aeruginosa*.

Urinary Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter diversus*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, and *Streptococcus faecalis*.

Infectious Diarrhea caused by *Escherichia coli* (enterotoxigenic strains), *Campylobacter jejuni*, *Shigella flexneri**, and *Shigella sonnei** when antibacterial therapy is indicated.

*Efficacy for this organism in this organ system was studied in fewer than 10 infections.

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing infection and to determine their susceptibility to ciprofloxacin. Therapy with Cipro® may be initiated before results of these tests are known, once results become available appropriate therapy should be continued. As with other drugs, some strains of *Pseudomonas aeruginosa* may develop resistance fairly rapidly during treatment with ciprofloxacin. Culture and susceptibility testing performed periodically during therapy will provide information not only on the therapeutic effect of the antimicrobial agent but also on the possible emergence of bacterial resistance.

CONTRAINDICATIONS

A history of hypersensitivity to ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin.

WARNINGS

CIPROFLOXACIN SHOULD NOT BE USED IN CHILDREN OR PREGNANT WOMEN. The oral administration of ciprofloxacin caused lameness in immature dogs. Histopathological examination of the weight-bearing joints of these dogs revealed permanent lesions of the cartilage. Related drugs such as nalidixic acid, cinoxacin, and norfloxacin also produced erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION).

PRECAUTIONS

General As with other quinolones, ciprofloxacin may cause central nervous system (CNS) stimulation, which may lead to tremor, restlessness, lightheadedness, confusion, and very rarely to hallucinations or convulsive seizures. Therefore, ciprofloxacin should be used with caution in patients with known or suspected CNS disorders, such as severe cerebral arteriosclerosis or epilepsy, or other factors which predispose to seizures (SEE ADVERSE REACTIONS).

Crystals of ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine of laboratory animals. Crystalluria related to ciprofloxacin has been reported only rarely in man, because human urine is usually acidic. Patients receiving ciprofloxacin should be well hydrated, and alkalinity of the urine should be avoided. The recommended daily dose should not be exceeded. Alteration of the dosage regimen is necessary for patients with impairment of renal function (SEE DOSAGE AND ADMINISTRATION SECTION IN FULL PRESCRIBING INFORMATION).

Drug Interactions Concurrent administration of ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions. If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate.

Antacids containing magnesium hydroxide or aluminum hydroxide may interfere with the absorption of ciprofloxacin, resulting in serum and urine levels lower than desired; concurrent administration of these agents with ciprofloxacin should be avoided.

Probencid interferes with the renal tubular secretion of ciprofloxacin and produces an increase in the level of ciprofloxacin in the serum. This should be considered if patients are receiving both drugs concomitantly.

As with other broad-spectrum antibiotics, prolonged use of ciprofloxacin may result in overgrowth of nonsusceptible organisms. Repeated evaluation of the patient's condition and microbial susceptibility testing is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Information for Patients Patients should be advised that ciprofloxacin may be taken with or without meals. The preferred time of dosing is two hours after a meal. Patients should also be advised to drink fluids liberally and not take antacids containing magnesium or aluminum concomitantly or within two hours after dosing. Ciprofloxacin may cause dizziness or lightheadedness; therefore patients should know how they react to this drug before they operate an automobile or machinery or engage in activities requiring mental alertness or coordination.

Carcinogenesis, Mutagenesis, Impairment of Fertility Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin and the test results are listed below.

Salmonella/Microsome Test (Negative)

E. coli DNA Repair Assay (Negative)

Mouse Lymphoma Cell Forward Mutation Assay (Positive)

Chinese Hamster V₇₉ Cell HGPR Test (Negative)

Syrian Hamster Embryo Cell Transformation Assay (Negative)

Saccharomyces cerevisiae Point Mutation Assay (Negative)

Saccharomyces cerevisiae Mitotic Crossover and Gene Conversion Assay (Negative)

Rat Hepatocyte DNA Repair Assay (Positive)

Thus, two of the eight tests were positive, but the following three *in vivo* test systems gave negative results:

Rat Hepatocyte DNA Repair Assay

Micronucleus Test (Mice)

Dominant Lethal Test (Mice)

Long-term carcinogenicity studies in animals have not yet been completed.

Pregnancy - Pregnancy Category C

Reproduction studies have been performed in rats and mice at doses up to six times the usual daily human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ciprofloxacin. In rabbits, as with most antimicrobial agents, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion. No teratogenicity was observed at either dose. After intravenous administration, at doses up to 20 mg/kg, no maternal toxicity was produced, and no embryotoxicity or teratogenicity was observed. There are, however, no adequate and well-controlled studies in

CONVENIENT B.I.D. DOSAGE

Recommended dosage schedule

| Infection Site* | Severity of Infection | Dosage |
|----------------------|-----------------------|---------------|
| Respiratory Tract* | Mild/Moderate | 500 mg B.I.D. |
| Bone and Joint* | Severe/Complicated | 750 mg B.I.D. |
| Skin/Skin Structure* | | |
| Urinary Tract* | Mild/Moderate | 250 mg B.I.D. |
| | Severe/Complicated | 500 mg B.I.D. |
| Infectious Diarrhea* | Mild/Moderate/Severe | 500 mg B.I.D. |

pregnant women SINCE CIPROFLOXACIN, LIKE OTHER DRUGS IN ITS CLASS, CAUSES ARTHROPATHY IN IMMATURE ANIMALS, IT SHOULD NOT BE USED IN PREGNANT WOMEN (SEE WARNINGS).

Nursing Mothers

It is not known whether ciprofloxacin is excreted in human milk; however, it is known that ciprofloxacin is excreted in the milk of lactating rats and that other drugs of this class are excreted in human milk. Because of this, and because of the potential for serious adverse reactions from ciprofloxacin in nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Ciprofloxacin should not be used in children because it causes arthropathy in immature animals (SEE WARNINGS).

ADVERSE REACTIONS

Ciprofloxacin is generally well tolerated. During clinical investigation, 2,799 patients received 2,868 courses of the drug. Adverse events that were considered to be drug related occurred in 7.3% of courses, possibly related in 9.2%, and remotely related in 3.0%. Ciprofloxacin was discontinued because of an adverse event in 3.5% of courses, primarily involving the gastrointestinal system (1.5%), skin (0.6%), and central nervous system (0.4%).

The most frequently reported events, drug related or not, were nausea (5.2%), diarrhea (2.3%), vomiting (2.0%), abdominal pain/discomfort (1.7%), headache (1.2%), restlessness (1.1%), and rash (1.1%).

Additional events that occurred in less than 1% of ciprofloxacin courses are listed below. Those typical of quinolones are italicized.

GASTROINTESTINAL

(See above), painful oral mucosa, oral candidiasis, dysphagia, intestinal perforation, gastrointestinal bleeding.

CENTRAL NERVOUS SYSTEM

(See above), dizziness, lightheadedness, insomnia, nightmares, hallucinations, manic reaction, irritability, tremor, ataxia, convulsive seizures, lethargy, drowsiness, weakness, malaise, anorexia, phobia, depersonalization, depression, paresthesia.

SKIN/HYPERSensitivity

(See above), pruritis, urticaria, photosensitivity, flushing, fever, chills, angioedema, edema of the face, neck, lips, conjunctiva or hands, cutaneous candidiasis, hyperpigmentation, erythema nodosum.

SPECIAL SENSES

blurred vision, disturbed vision, (change in color perception, overbrightness of lights), decreased visual acuity, diplopia, eye pain, tinnitus, bad taste.

MUSCULOSKELETAL

joint or back pain, joint stiffness, achiness, neck or chest pain, flare up of gout.

RENAL/UROGENITAL

interstitial nephritis, renal failure, polyuria, urinary retention, urethral bleeding, vaginitis, acidoses.

CARDIOVASCULAR

palpitations, atrial flutter, ventricular ectopy, syncope, hypertension, angina pectoris, myocardial infarction, cardiopulmonary arrest, cerebral thrombosis.

RESPIRATORY

epistaxis, laryngeal or pulmonary edema, hiccup, hemoptysis, dyspnea, bronchospasm, pulmonary embolism.

Most of these events were described as only mild or moderate in severity, abated soon after the drug was discontinued, and required no treatment.

In several instances, nausea, vomiting, tremor, restlessness, agitation, or palpitations were judged by investigators to be related to elevated plasma levels of theophylline possibly as a result of a drug interaction with ciprofloxacin.

Adverse Laboratory Changes Changes in laboratory parameters listed as adverse events without regard to drug relationship.

Hepatitis - Elevations of: ALT (SGPT) (1.9%), AST (SGOT) (1.7%), alkaline phosphatase (0.8%), LDH (0.4%), serum bilirubin (0.3%).

Hematologic - eosinophilia (0.6%), leukopenia (0.4%), decreased blood platelets (0.1%), elevated blood platelets (0.1%), pancytopenia (0.1%).

Renal - Elevations of: Serum creatinine (1.1%), BUN (0.9%).

CRYSTALLURIA, CYANLURIA, AND HEMATURIA HAVE BEEN REPORTED.

Other changes occurring in less than 0.1% of courses were: Elevation of serum gammaglutamyl transferase, elevation of serum amylase, reduction in blood glucose, elevated uric acid, decrease in hemoglobin, anemia, bleeding diathesis, increase in blood monocytes, and leukocytosis.

OVERDOSAGE

Information on overdosage in humans is not available. In the event of acute overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage. The patient should be carefully observed and given supportive treatment. Adequate hydration must be maintained. In the event of serious toxic reactions from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of ciprofloxacin from the body, particularly if renal function is compromised.

DOSAGE AND ADMINISTRATION

The usual adult dosage for patients with urinary tract infections is 250 mg every 12 hours. For patients with complicated infections caused by organisms not highly susceptible, 500 mg may be administered every 12 hours.

Respiratory tract infections, skin and skin structure infections, and bone and joint infections may be treated with 500 mg every 12 hours. For more severe or complicated infections, a dosage of 750 mg may be given every 12 hours.

The recommended dosage for infectious diarrhea is 500 mg every 12 hours.

In patients with renal impairment, some modification of dosage is recommended (SEE DOSAGE AND ADMINISTRATION SECTION IN FULL PRESCRIBING INFORMATION).

HOW SUPPLIED

Cipro® (ciprofloxacin HCl/Miles) is available as tablets of 250 mg, 500 mg, and 750 mg in bottles of 50, and in Unit-Dose packages of 100 (SEE FULL PRESCRIBING INFORMATION FOR COMPLETE INFORMATION).

*Due to susceptible strains of indicated pathogens. See indicated organisms in Brief Summary.

For further information, contact the Miles Information Service:
1-800-642-4776. In VA, call collect: 703-391-7888.

COMMITTED TO THERAPEUTIC EFFICIENCY



Miles Inc.
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Community Forum

This and That About Pharmacy

Leon Weiner, P.D.

NEWS IN BRIEF . . .

Sidney B. Seidman ('57) and a graduate of medical school has recently associated with Anthony Vazzano, M.D. of Reisterstown. Their practice is in pediatric and adolescent medicine.

Jack Barshack ('33), has sold Aero Pharmacy located in Middle River to Harvey Goldberg ('73). In addition to his 43 year connection with Aero Pharmacy, Jack has also been involved with four other drug stores located in Virginia, Washington, and Maryland.

Phillip Paul Weiner ('61) wrote an article entitled "How Our Newsletter Recommends Products to Physicians" which appeared in the May 1988 issue of *Pharmacy Times*. Phil is the owner of Weiner's Pharmacy in Pikesville.

Jay R. Brinsfield ('58) was recently profiled in the Delaware Business Review. He is the president and sole stockholder of Matthews Hallmark Gift and Card Shop in Montchanin, Delaware. Matthews lays claim to being the country's largest independent Hallmark dealer. More than 70 percent of the company's retail greeting card and gift business involves selling Hallmark products. Brinsfield bought the Delaware business in the mid-70's from the Matthews family and later sold off its office supply division to concentrate on consumer retailing.

PHARMACY CHANGES AS OF JUNE 1988

NEW PHARMACIES:

Belair Apothecary, Inc.
2105 Laurel Bush Road
Belair, MD 21014

Harford Medical Services, Inc.
2105 Laurel Bush Road
Belair, MD 21014

Continued on Page 36.

SEPTEMBER, 1988

CONGRATULATIONS . . .

To: Lance Berkowitz ('65-MCV) who was recently appointed to the State Board for Community Colleges by Governor Schaefer. Lance is the new owner of Arcade Pharmacy at 5500 Harford Road in Baltimore. Lance is a much honored community volunteer who has written for numerous publications and has appeared on radio and television speaking on health care issues. Currently, he is writing a column for the Herald-Gazette, a community newspaper in North-northeast Baltimore.

To: Thomas P. Evans ('83) who has recently become the new director of pharmacy at Mount Washington Pediatric Hospital. Previously he was employed at Johns Hopkins, Maryland General and Franklin Square hospitals.

To: Marvin Edell ('54) who opened a new pharmacy in Longneck, Delaware. He is the former owner of Carter Drug in Baltimore.

To: Madlyn Fass Kruh ('75) who was recently installed as chairman of the executive committee for the Chesapeake Region of Women's American ORT (Organized for Rehabilitation Through Training). She is a former state employee for Medical Assistance.

PHARMACY PASSINGS . . .

Emanuel V. Shulman ('29), 82, a retired pharmacist who owned and operated a drugstore in Washington for more than 40 years, died of cancer June 16, 1988 at George Washington University Hospital. Shulman was born in Baltimore. He graduated from Johns Hopkins University and the University of Maryland where he received a master's degree in botany and doctoral degrees in pharmacy and pharmacognosy. After graduating, he taught at the University of Maryland before moving to Washington in 1937. He sold the store and retired in 1985.

Gilbert M. Carouge ('44), 68, retired chief medical officer for the Chessie Rail System, died May 5, 1988 of a heart attack caused by complications from leukemia. A native of Baltimore, he was a 1937 graduate of City College before attending pharmacy school. After service in the Navy during World War II he worked as a pharmacist to put himself through the University of Maryland Medical School from which he graduated in 1947.

Edward J. Alessi ('31), 77, passed away on February 8, 1988. Four years after graduating from pharmacy school, he graduated from the University of Maryland Medical School in 1935. Dr. Alessi was a general practitioner in Hamilton for 41 years. He was a member of the Wedgewood Club.

LOVE AND MARRIAGE

Stefanie Czapiewski and Beryl Stoler were married in May 1988. Beryl is the son of Mr. and Mrs. Myer Stoler ('38).

Marlene Ades was Married to Dr. Jonathan Aarons, son of Mr. and Mrs. Hillel Aarons ('53). Hillel is the former owner of Hertz Pharmacy in Baltimore County.

Victoria Louise Strohmeyer recently wed Allen Lawrence Karpe ('83). Allen is an assistant director of pharmacy with Valu Food Stores.

Amy Zucker ('88) and Dr. Malcom J. McDonald of Birmingham, England are planning to wed in September. She is the daughter of Sarah and Paul Zucker. Paul ('58) is a partner in Burris and Kemp Pharmacy in Baltimore. Amy is working for Peoples in Columbia, MD. April 1988.

Fran Belman and Alan Surell are due to wed in October. He is the son of Mr. and Mrs. Howard Surell. Howard ('47) is currently working for Rite Aid.

PHARMACY CLOSINGS:

People's #1259
3314 Walters Lane
Forestville, MD 20747

Pharmacy at O'Donnell Square
2920 O'Donnell Street
Baltimore, MD 21224

Capitol Drugs
206 West Street
Annapolis, MD 21401

Travacare Pharmacy Services
Suite L, 6655 Amberton Drive
Baltimore, MD 21227

Total Home Nutrition Pharmacy
8925 McGaw Court, Suite 9
Columbia, MD 21045

NAMES AND OWNERSHIP CHANGES:

Homewood Hospital Center Pharmacy
2724 North Charles Street
Baltimore, MD 21218
(Formerly North Charles General Hospital Pharmacy)

Homewood Hospital Center Pharmacy
3100 Wyman Park Drive
Baltimore, MD 21211
(Formerly Wyman Park Health System Pharmacy)

NAMES AND LOCATION CHANGES:

Mail Order Prescription Services
111 Cherry Hill Road
Baltimore, MD 21225
(Formerly Medical Center Pharmacy)

Good business fact #5



Sandoz gets good advice to give you better service

Because we're always looking for new ways to serve you better, we draw on the expertise of three professional advisory boards: Consultant Pharmacists, Hospital Pharmacists, and Retail Pharmacists. What we learn helps us devise programs and policies that are in your best interests. And that's the bottom line.

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doing business with Sandoz**



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Sandoz Pharmaceuticals Corporation
East Hanover, NJ 07936

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Get even.

If you're billing people who persist in not paying, you have every reason to be upset. The collection specialists at I.C. System will see that you get satisfaction.

What's more, we'll see that you get justice. By reporting your delinquent debtors to the five national reporting services, we could severely impact their ability to get credit.

We're I.C. System, and we promise results. In fact, our work is endorsed by over 1,200 professional and trade associations, including yours. And no matter where you're located or where your debtors live, we have local representatives to service your account.

But most important, we guarantee results, by collecting *at least ten times the amount of our retainer*.

To find out how the I.C. System approach can work for you, call toll free (800) 824-9469, ext. 330. In Minnesota, call (612) 483-8201, ext. 330.

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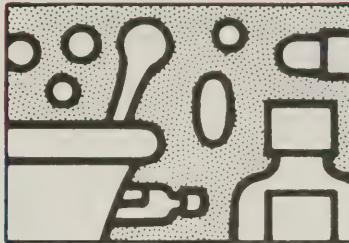
3384-2

Patient Aid

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

Things You Should Know FOR YOUR GOOD HEALTH



What is physical fitness and how is it achieved?

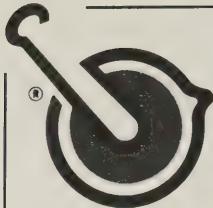
For many people, fitness is almost synonymous with health and attractiveness. More people are striving to be fit, and yet, in spite of the widespread use of the term "fit," there is no universally accepted definition for it. A general definition of physical fitness would be: "The ability to do an activity without undue strain." In a sense, each kind of exercise endeavor defines a different kind of fitness. A runner is fit for running, but could never lift the amount of free weight that a weight-lifter or football player could. Each is "fit" for a particular kind of endeavor.

Physical fitness is comprised of certain qualities — flexibility, strength, and "aerobic stamina." Flexibility and strength are fairly straightforward concepts, and can be attained through stretching and strength-building exercise. "Aerobic stamina," on the other hand, is frequently misunderstood. Literally, "aerobic stamina" refers to the amount of endurance one possesses while exercising in an atmosphere of air which contains oxygen. "Aerobic stamina" is associated with the heart and lungs working at greater efficiency. It leads to the type of fitness that may help prevent atherosclerosis (hardening of the arteries), sudden death and heart attack by improving the "risk factors" for atherosclerosis. Improved fitness can lower the blood pressure in normal people and in those with mild to moderate hypertension. In addition, the development of physical fitness may help lower the blood cholesterol level. There is some evidence that fitness lessens the impact of diabetes on the cardiovascular system. Thus, achieving physical fitness may improve health, help prevent premature death and disability and may delay some

aspects of the aging process.

Physical fitness is pursued by activities that cause the heart, lungs and the body's larger muscles to do work. There are three criteria that determine whether an activity is sufficient to attain physical fitness. These are INTENSITY, DURATION, and FREQUENCY. In general, the greater the intensity of an activity the less duration and frequency of that activity is required in order to become fit. However, if the activity is too intense, it may cause injury. Most exercise prescriptions recommend activity that is sufficient to make the heart work at 70 to 85 percent of its maximum rate, for 30 to 40 minutes, three times a week. For a healthy person not taking any medication, a rough rule of thumb for estimating maximum heart rate is to subtract the patient's age from 220. (For example, a 40 year old person could estimate his heart rate as $220 - 40 = 180$. His exercise training range, 70 to 85 percent of that, is between 126 and 153). However, if one has a chronic illness or if one is taking medication, then the only safe and accurate way to find the maximum heart rate is to have an exercise stress test performed. Working at a lower intensity (i.e., a lower heart rate) can help one attain fitness, but it will take longer.

Persons over the age of 40 years or with any history of a heart problem or significant risk factors for heart disease, should consult a physician before starting a vigorous exercise program. In beginning an exercise program, it is important to start slowly and build up the activity gradually. It's For Your Good Health. **Reprinted from Heartbeat of the Chicago Heart Association.**



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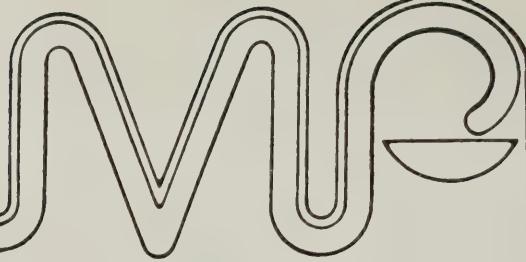
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Elwin Alpern, P.D.

President

President's Tip

October is national "Talk About Prescriptions Month." This is an excellent time to promote the service aspect of our profession that too many of our patients overlook. Be sure and check out the articles on literacy and patient compliance as well as the pull-out section of special promotional aids.

Continuing Education

Beginning with this issue of *The Maryland Pharmacist*, our continuing education articles will enable you to earn 1 credit hour (0.1 CEU) towards fulfillment of your C.E. requirements. Read the article carefully and then complete the quiz that appears on page 30. Return the quiz to the MPhA offices as instructed on the quiz.

Correspondence Course

Advising Consumers on OTC Calcium Supplements and Osteoporosis

by Thomas A. Gossel, R.Ph., Ph.D.

Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss the possible role of calcium in prevention of osteoporosis; and
2. explain important points about the etiology of osteoporosis.



Gossel

Wuest

Objectives

At the conclusion of this lesson, the participant will be able to:

1. define the role of calcium in preventing osteoporosis;
2. exhibit knowledge about the etiology and prognosis of osteoporosis;
3. demonstrate an understanding of the relationship between calcium, estrogen and vitamin D in bone physiology;
4. choose from a list of OTC calcium supplement products, an appropriate one when a particular salt is requested;
5. identify information that pharmacists can use to counsel consumers about OTC calcium supplement products.

Over 133,000 women in the U.S. will experience a hip fracture this year. Twenty-seven thousand of them will develop complications; more than half will die within three months. The cause, osteoporosis, is the most common skeletal disorder in the world.

Calcium supplementation is a current fad. Some refer to it as the "vitamin C of the 80s." Annual sales of OTC calcium supplement products are estimated to be nearly \$200 million. While some of these items are purchased for other uses, most of the calcium is taken by women believing it will prevent the onset of osteoporosis.

This article will assist pharmacists in counseling consumers on the safe use of OTC calcium supplements. It describes the physiologic role and pharmacologic action of calcium on the skeleton. It discusses osteoporosis and illustrates how calcium supplements and other components of therapy may benefit individuals with this condition. It also lists important consumer information for persons interested in self-medicating with OTC calcium supplements.

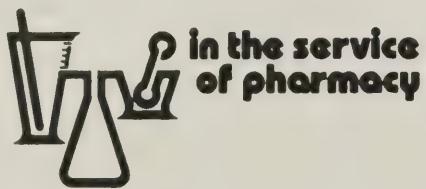
Physiologic Role of Calcium in Bone Development

At the National Institutes of Health (NIH) Consensus Development Conference on Osteoporosis in April, 1984, it was reported that dietary calcium played an important role in prevention and treatment of osteoporosis. It was also announced that the diets of American women were insufficient in calcium, and that these women would benefit by supplementing their dietary intake.

Skeletal bone is composed of two types of structures: trabecular and cortical. **Trabecular** (medullary) bone contains a spongy, porous network of trabeculae, or struts. These transverse the structure and provide strength.

Cortical bone is compact, dense and solid, and has few underlying trabeculae. All bones contain both forms, trabecular structure within, and cortical bone around it. Different bones have various proportions of each type.

For example, trabecular bone predominates in the vertebrae, proximal femur (hip) and wrist. Cortical bone comprises most of the long bones of the skeleton. Trabecular bone mass is lost to a greater extent in osteoporosis than cortical bone. Consequently, fractures of the vertebrae, hip and wrist are common with this disorder.



This continuing education for Pharmacy article is provided through a grant from

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Bone growth is dynamic. Bone consists of two important cells that regulate calcium metabolism: osteoblasts and osteoclasts. The **osteoblast** synthesizes bone collagen and other supporting components of the bone matrix, controls mineralization, and directs osteoclastic activity. The **osteoclast** resorbs bone (i.e., releases calcium from bone structure). Throughout life, the skeleton is continually being formed by osteoblasts, and reclaimed by osteoclasts. Osteoblastic action predominates early in life to the mid-30s. At this point, osteoclasts assume the more dominant activity.

There then is a gradual net loss of both types of bone, which accelerates following menopause. The loss proceeds at 0.5 percent/year in both sexes. After menstruation ceases, loss accelerates to 1 to 1.5 percent/year. Men lose it approximately half as fast. By age 65, 50 percent, and age 85, 100 percent of all women have a bone density below the normal fracture threshold.

Dietary Sources of Calcium

The U.S. RDA for calcium is 1,000 mg/day for women 19 and over. Postmenopausal women may require 1,200 to 1,500 mg/day. More than 65 percent of women age 18 to 30, and more than 75 percent of women over 35 do not meet the RDA for calcium. The actual intake for adult Americans is closer to 450 to 550 mg/day.

Table 1 lists dietary sources of calcium. Milk, cheese and other dairy products, fish such as sardines and salmon with edible bones, and green leafy vegetables (except spinach) are rich in calcium.

Calcium must be in its ionic form to be absorbed. Gastric acid increases its ionization (i.e., solubility), as does vitamin C and some of the amino acids. But a high fat diet may inhibit absorption by forming insoluble soap with calcium, which are then excreted in the feces.

Additionally, calcium absorption is impaired by diets rich in phosphate from grains and foods rich in oxalate and phytate such as cocoa, spinach and soy beans. High-protein foods enhance fecal calcium loss. Individuals with lowered bone mineralization may have a dietary history of consumption of such foods.

The lactose in milk forms a soluble

compound with calcium. This enhances the value of milk as one of the best food sources of the mineral (remember, too, that milk is fortified with vitamin D which also enhances calcium absorption).

Osteoporosis

Osteoporosis is reported to be the most common skeletal disorder in the world. It is described as a debilitating degeneration of bone. The affliction actually represents a group of diseases that are characterized by decreased bone mass.

Two descriptive terms for osteoporosis appear in advertising and the literature. **Postmenopausal osteoporosis** describes the affliction that develops between menopause and age 65.

Senile osteoporosis denotes the condition that develops in women and men after age 65. There is neither physiologic nor pathologic differentiation between them, just an arbitrary age difference.

All population groups experience osteoporosis. But there are race and sex-related differences. Approximately 30 percent of Caucasian women develop symptomatic osteoporosis (shown by fractures). Bone loss accelerates after menopause, and the incidence of fractures is higher in women than men. Women are more prone to osteoporosis because they have 30 percent less bone

mass than men. Other risk factors for osteoporosis are listed in Table 2.

The most debilitating physical outcome of osteoporosis is a decrease in stature with resultant deformity. Affected persons acquire the characteristic stooped posture and hunched back (dowager's hump), resulting in a loss of 2 to 8 or more inches in height (Figure 1). Additionally, spinal compression fractures may cause difficulty in walking and breathing, and place stress on adjacent tissues to cause severe chronic pain. The cosmetic effects of physical deformity may result in serious emotional problems.

It is estimated that 190,000 spinal fractures in the U.S. each year in women age 45 or over are attributed to osteoporosis. One study of symptomatic osteoporotic women reported that 95 percent experienced more than six vertebral fractures during a 10-year period. Additionally, 133,000 hip fractures occur each year from osteoporosis. Wrist fractures, while less serious, are also common, with approximately 100,000 osteoporotic patients experiencing these each year.

Etiology. Numerous theories have been proposed to explain disease development. A leading hypothesis is that bone resorption in osteoporosis (from any cause) induces hypercalcemia. This in turn decreases parathyroid hormone (PTH) secretion.

Table 1

Calcium Content of Selected Foods

| Food | Serving Size | Calcium (mg) |
|--|---------------------------|--------------|
| Plain, low-fat yogurt | 8 ounces | 415 |
| Canned sardines, with bones | 3 ounces | 371 |
| Part skim-milk ricotta cheese | ½ cup | 334 |
| Skim milk | 1 cup | 302-316 |
| 2% low-fat milk | 1 cup | 297-313 |
| Swiss cheese | 1 ounce | 272 |
| Soft-serve ice cream | 1 cup | 236 |
| Nonfat dry milk | ¼ cup | 209 |
| Cheddar, Muenster, or part skim-milk mozzarella cheese | 1 ounce | 203-207 |
| Fried oysters, dipped in egg, milk, bread crumbs | 4 oysters | 196 |
| Slivered almonds | ½ cup | 179 |
| Cooked, chopped collards | ½ cup | 178 |
| Pasteurized process American cheese | 1 ounce | 174 |
| Canned salmon, with bones | 3 ounces | 167 |
| Feta cheese | 1 ounce | 140 |
| Cooked broccoli | ¾ cup | 132 |
| Tofu | 1 piece (2½ × 2¾ inch) | 108 |

From: FDA Consumer, October, 1986

Table 2**Risk Factors for Osteoporosis**

- Female
- Family history of osteoporosis
- Short stature and small bones
- Early menopause
- Caucasian, Northern European or Oriental race
- Inactivity; sedentary life-style
- Smoking
- Low dietary calcium intake
- High protein diet
- Intolerance to milk and dairy products
- Leaness
- Increasing age
- Nulliparous
- Excessive alcohol consumption
- Excessive caffeine intake

PTH activates osteoclasts, and is required for transformation of vitamin D into 1,25-dihydroxycholecalciferol, its active form. This active metabolite of vitamin D is required for intestinal absorption of calcium.

Estrogen contributes significantly to maintaining normal calcium homeostasis. Its precise contribution is unknown, but it does stimulate

formation of 1,25-dihydroxycholecalciferol. With its loss at menopause, bone becomes more sensitive to PTH, and calcium is mobilized from it more easily, resulting in lowered structural strength.

Calcium Supplements

Despite uncertainty about the effectiveness of calcium supplements, especially when taken without a physician's guidance, they are generally well tolerated and have few contraindications. Clinical trials so far have revealed controversial results as to whether bone loss can be prevented with calcium supplements alone.

Evidence shows that while calcium supplementation by itself may slow bone loss, it neither prevents loss nor leads to increased bone mass. Self-treatment with calcium supplements should therefore be considered as adjunctive to other measures, rather than as treatment for osteoporosis.

The beneficial action of supplements may be due to calcium decreasing PTH secretion. This resultant decrease, in turn, slows bone

calcium resorption, and retards the osteoporotic disease process.

Table 3 lists representative OTC calcium supplement products. Table 4 shows the comparative calcium content of various salts. The chemical form of each calcium supplement should be considered, and its dosage adjusted, when calculating the amount of calcium needed. It has not been proven whether certain calcium salts are superior to others.

Overall, calcium carbonate may have the greatest advantage since it contains the largest percentage of calcium. Calcium carbonate is derived from pulverized oyster shells, or manufactured by chemical precipitation. There is no proven difference between either form. It is insoluble *per se* and must be converted to absorbable calcium chloride by the action of HCl in the stomach. The solubility of phosphate salts (dibasic calcium phosphate, tribasic calcium phosphate) is also decreased as the acidity of the stomach increases.

Adverse Effects and Toxicity. These are rare and most are mild. They include nausea, constipation and bloating.

Of greater pathologic significance is the chance for induction of calcium urolithiasis (kidney stones). This is especially important in persons with hypercalciuria such as may occur in osteoporosis. Hypercalciuria also occurs with dietary or pharmacologic calcium supplementation. Individuals who have a history of kidney stones should consult a physician before beginning calcium supplementation.

The interactions involving simultaneous administration of calcium with other drugs are well documented. For example, atenolol, iron salts, salicylates and tetracycline are significantly affected. Absorption of other drugs may likewise be reduced.

Role of Estrogen

Numerous studies have shown that estrogen therapy inhibits bone loss of calcium in postmenopausal women. The current theory of why this occurs is that estrogen increases depressed calcitonin levels. In healthy individuals, calcitonin and PTH counterbalance each other's actions to allow for continuous dynamic interchange of bone calcium with ionic calcium. Menopausal changes

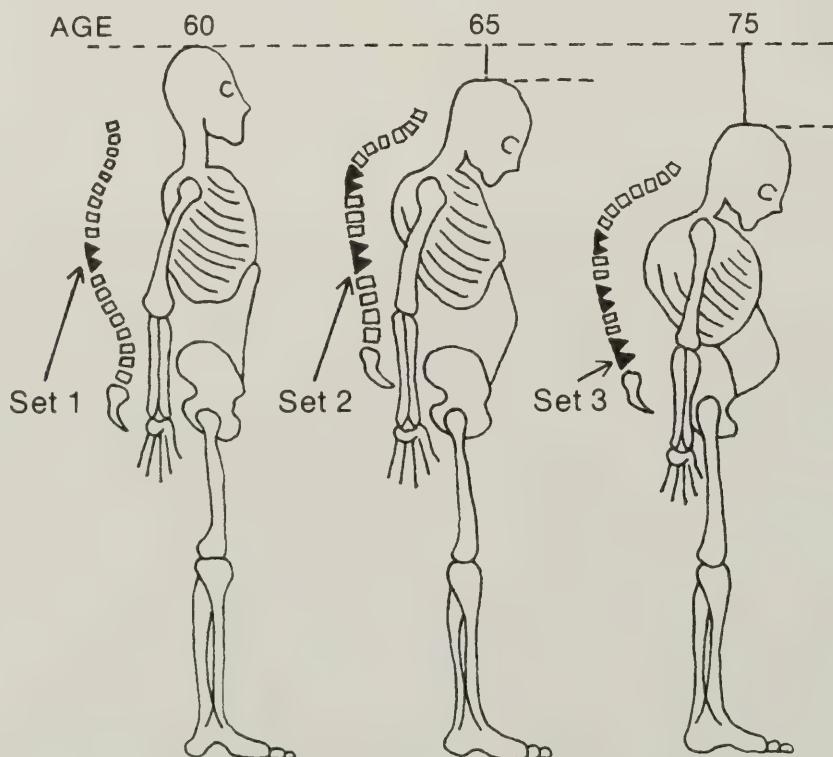


Figure 1. Formation of "Dowager's Hump" shown as progressive demineralization of vertebrae (Sets 1, 2, and 3).

Table 3

Representative OTC Calcium Supplements

| | | |
|--|---|--------------------------------------|
| BioCal (Miles Labs) | Caltrate 600 with Vitamin D (Lederle) | Os-Cal 500 (Marion) |
| Calcium Gluconate (various) | Ca-plus Protein* (Miller) | Oyst-Cal 500 (Goldline) |
| Calcium Gluconate with Vitamin D (Lilly) | Citracal (Mission) | Oyst-Cal D (Goldline) |
| Calcium Lactate (various) | Dibasic Calcium Phosphate (Lilly) | Oystercal-D 250 (Nature's Bounty) |
| Calcium Carbonate (various) | Elecal** (Western Research) | Oystercal 500 (Nature's Bounty) |
| Calciday-667 (Nature's Bounty) | Florical*** (Mericon) | Posture (Ayerst) |
| Calel-D (USV) | Neo-Galglucon (Dorsey) | Posture-D (Ayerst) |
| Cal-Sup (3-M Personal Care) | Os-Cal 250 (Marion) | Suplical (Parke-Davis) |
| Caltrate 600 (Lederle) | | Theracal (Parke-Davis) |
| | | Tums (Norcliff Thayer) |

*Complexed with amino acids from soy

**Also contains 15 mg magnesium

***Also contains 8.3 mg sodium fluoride

appear to cause an imbalance in their ratio leading to the osteoporosis seen in some elderly women.

Some investigations have revealed that estrogen/progestogen combinations may actually promote bone formation and increase bone mass. In a crossover trial that compared an estrogen/progestogen combination with placebo, bone density increased in the treatment group and decreased in the placebo group over the three years of the study. When some women in the treatment group were switched to placebo, their bone mineral content decreased. Conversely, when women in the placebo group were switched to therapy, bone mineral content increased.

Adding progesterone for 7 to 13 days at the end of an estrogen regimen reduces estrogen-induced hyperplasia of tissue. It is felt this will counter the risk of endometrial cancer.

Role of Vitamin D

Vitamin D is required to assure optimal calcium absorption. Low levels of the vitamin have been implicated in causing osteoporosis. The body's need for this vitamin increases with age since intestinal absorption of fat-soluble vitamins decreases. Its RDA for adults is 200 IU/day.

Reduced levels result in increased PTH release and, thus, enhanced

bone loss. Still, investigation has generally failed to show little or any benefit of supplementing calcium intake with vitamin D.

If a vitamin D deficiency is demonstrated, however, replacement is warranted. Doses should not exceed 400 to 600 IU/day.

Advising Consumers

Weight-bearing exercise is important for preventing and treating osteoporosis. Physical activity enhances bone mineralization.

The different calcium salts provide various quantities of elemental calcium. When comparing one product to another, the amount of elemental calcium, rather than the total quantity of salt, should be used as the reference point.

Smoking can interfere with calcium absorption. Menopause often occurs earlier in women who smoke. Alcohol may decrease calcium absorption. Drinking as few as two alcoholic beverages daily seems to increase the risk of osteoporosis.

Consumers should also be alerted to a potential danger of self-treatment with calcium supplements if they are taking prescription medication containing large doses of vitamin D or a thiazide diuretic. A physician may prescribe vitamin D to treat bone disease and a thiazide diuretic for hypertension.

Vitamin D enhances calcium absorption; thiazides reduce urinary calcium excretion. The diuretic's effect is accentuated in patients who have conditions such as osteoporosis that are associated with augmented bone resorption. For example, a study reported that 5 of 12 subjects developed hypercalcemia when they took both a calcium supplement and a thiazide derivative. The same study also reported a 21-year-old osteoporotic woman who took vitamin D, 120,000 IU/day, and elemental calcium, 2 gm/day. Hypercalcemia occurred only after chlorothiazide was added to her regimen.

Calcium supplementation is preventive, rather than therapeutic. It must be started at an early age and be continued thereafter. Physical symptoms of osteoporosis appear insidiously. Once the height decreases or dowager's hump appears, they are neither treatable with calcium, nor reversible.

Table 4

Comparative Calcium Content of Various Foods

| Salt | % Calcium | Gram of Salt Needed to Provide 1000 mg Elemental Calcium |
|----------------------------|-----------|---|
| Calcium carbonate | 40 | 2.5 |
| Tribasic calcium phosphate | 38.8 | 2.6 |
| Calcium sulfate | 36.1 | 2.8 |
| Dibasic calcium phosphate | 29.5 | 3.4 |
| Calcium citrate | 24.1 | 4.15 |
| Calcium lactate | 18.4 | 5.4 |
| Calcium ascorbate | 10.3 | 9.75 |
| Calcium gluconate | 9.3 | 10.75 |

Is Reading Ability Affecting Your Patient's Therapy?

A recent letter in *The Lancet* tells the story of a doctor and his female patient. Her seriously elevated blood pressure did not improve despite weekly office visits and medication adjustments. When she ultimately had to be hospitalized, her blood pressure came under immediate control—using the same drug regimen the doctor had prescribed. What made the difference? The patient could not read. On her own, she had been *unable* to follow the multi-drug therapy as directed.

Far from being an uncommon situation, estimates suggest that at least 20 percent of Americans, or one in every five, cannot read well enough to carry out their medication treatment correctly at home. (See box, "Don't Assume Your Patients Read With Understanding.") Added to the problem are patients with poor eyesight and those whose primary language is not English.

In fact, communicating well with illiterate patients has become recognized as a critical public health challenge in the 1980's. The potential for adverse medication outcomes due to functional illiteracy may prove greater than the health threat from other problems that have traditionally received more attention.

For example, health professionals are well trained to ask patients routinely about penicillin sensitivity. This condition affects only about 10 percent of the population, or *half* the number with literacy problems. Yet when was the last time you made sure a patient could read the directions on his medicine bottle?

Despite its serious potential consequences, illiteracy is an easy condition for health care professionals to overlook. Most poor readers are embarrassed about their problem and do not readily admit that they cannot read. For this reason, illiterate Americans have been called the "caste of invisibles."

Many people hold stereotypes about people with low literacy skills that inhibit identifying and helping to overcome communication problems. The stereotype envisions illiterates as school drop-outs or recent immigrants.

In reality, poor reading skills are found in every part of the country, in every walk of life, and among every population group. Many illiterate people are highly intelligent, as demonstrated by their ability to hold jobs and get through life without a critical basic skill. Al-

though dropping out of school early is one reason for poor reading, it is only one of many, including physical and learning disabilities, lack of interest at the time of instruction, ineffective teaching—even television has been implicated in the characteristic decline in reading skills that many people experience after leaving school.

What is it like to have low literacy skills? If you are a poor reader, you read very slowly, letter-by-letter and word-by-word. Your vocabulary is small, and you will have trouble describing symptoms such as pain. You often skip words or read out of sequence and you may miss the context of the information.

Try reading backwards to get an idea of the poor reader's situation.

Don't Assume Your Patients Can Read With Understanding

- More than 27 million Americans over age 17 are "functionally illiterate." This means they can't read or write well enough to understand a medicine label or read a poison warning.
- In absolute numbers, the largest illiterate population in the U.S. is native-born white Americans.
- Of all adults classified as illiterate:
 - 41% live in central cities or metropolitan areas, compared to 8% in rural areas.
 - 56% are under age 50
 - 37% speak of non-English language at home.
- About 26% of native-born Americans over the age of 60 cannot read.
- More women than men are illiterate.
- About 40% of minority youth are functionally illiterate; compared to about 13% of all 17 year olds.
- Half of all Americans read below the 10th grade level.

The sociologic literature points up additional problems those with poor communication skills face. The low literacy patient has difficulty relating to abstract or general points; he or she can best comprehend concrete terms related to known personal experience (see article "How to Teach Low Literacy Patients About Their Medications.") Many times these patients do not realize that they need to give information to the

health professional, because they do not usually think in terms of clarification or explanation. When they do offer statements, the information is likely to be in bits and pieces, without logical flow. It is also hard for low literacy patients to handle complicated charts or tables, which many well-intentioned materials use as a way of avoiding too much prose.

How can you identify patients with poor literacy skills? There are a variety of formal evaluation tools, such as the Wide Range Achievement Test for word recognition and the Cloze test of reading comprehension. Obviously, however, it is not always feasible to administer such tests in a clinical situation.

Literacy experts suggest that some patient behaviors can alert the professional to suspect a reading deficiency: The patient who says I "forgot my glasses" when a need for reading occurs or who wants to "let his wife see it first;" the patient who brings in a signed

check and asks you to fill in the amount, or the patient who spends a long time in a pharmacy aisle trying to find an over-the-counter package recognizable by color and shape. Some believe that whenever patients don't comply with instructions, providers should consider the possibility of functional illiteracy as a contributing factor.

Once identified, approaching the problem tactfully is important. Experienced practitioners suggest asking the patient to repeat written instructions or label directions "to be sure you understand." Others read instructions to any suspected poor readers, explaining that "the type is so small many people have trouble with it."

Most importantly, people with poor communication skills *can* learn about their medicines and take an active role in treatment. Appropriate oral and written communication is the key.

How to Teach Low Literacy Patients About Their Medicines

Patients with low literacy levels need simple, well-designed information. Those who cannot read at all need easy-to-understand verbal counseling, supplemented with nonverbal visual aids. Poor readers also need simple verbal instructions coupled with written material that communicates at a low reading level. The following are points to keep in mind in targeting information to patients with poor communication skills.

Keep it Short

- Present the smallest amount of information possible to do the job, and no more than three new points at any one time.
- Keep your sentences short; eight to ten words is ideal. In written materials, keep paragraphs to three or four sentences.
- Try to use words of two syllables or less. This automatically stops you from using too many technical terms.

Keep it Simple

- Focus only on the main points and avoid the tangential details.
- Teach vocabulary when use of medical terms is unavoidable. However, present no more than seven words at a time, the most that the short-term memory can absorb.
- Group medication information points in "chunks," and introduce no more than three or four points per category.

- Present written information at the *fourth or fifth grade* level or lower. You can assess the reading level of materials by using a readability formula or computerized aids (see Resources page.) As a comparison, many surgical consent forms are written at the 16th grade level; *The New York Times* has about a 12th grade reading level; instructions on an aspirin bottle are at the 10th grade level; most patient health information is at the 10th grade level or above.
- Keep visuals clean. Avoid fancy type, distracting lines, or curly cues, and vertical lettering.
- Avoid distracting the poor reader's eye with abbreviations, contractions, acronyms, and quotation marks.
- Adapt high level health education materials you have on hand for poor readers. Pick one, two or three important points; summarize them briefly or highlight with circles and arrows.

Be Logical

- Give patients the most important information points first and last; studies show that patients will remember these points best.
- Sequence information in the way that the patient will use it. You may use steps (1, 2, 3); a chronological order (6 AM, noon, 6 PM); or topical arrangement (main heading with subheadings).
- Give patients information they can use immediately; it will help them to remember if they fill out

a medication chart as soon as they get home or go right to the pharmacy for a prescription renewal.

Be Concrete

- Remember that even common words can confuse patients unless explained in concrete terms, perhaps including demonstrations. In one study of prescription label comprehension, patients misinterpreted words in daily usage, such as "anxiety," "tablespoonful," "teaspoonful," "tablet," and "capsule."
- Don't use abstract words or phrases. For example, instead of "Don't stop taking your medication too soon," say "take one tablet a day. Don't stop until the bottle is empty."
- Use non-verbal graphic aids such as color-coding medication bottles, simple charts, reminder aids, and medication calendars that use visual symbols.
- Make instructions time-specific. Instead of saying take the medicine three times a day, say take it at 7 am, 1 pm, and 7 pm.
- Use only universally recognized symbols in presenting instructions graphically. Studies show that not all symbols are easy to understand for low literacy patients. Pretesting for comprehension is essential; university departments of education, library science, and nursing can help.

Repeat

- At the end of each information "chunk" you teach, restate the message and demonstrate the how-tos. Don't move on to a new topic until you are sure the patient has understood.
- Ask the patient to repeat back important points in his or her own words. Have patients demonstrate where appropriate.
- Recap written instructions at the end of each section.
- Use words consistently. For example, avoid using medicine, drug, and pill interchangeably as you might do for variety with a more literate audience.

Keep It Interesting

- Speak and write in a conversational style. Patients relate to it, and it automatically keeps the reading level lower.
- Keep information relevant to the patient's situation. This includes showing sensitivity to cultural differences, which can inhibit comprehension of instructions.
- Use active verbs and concrete nouns. Avoid adjectives and adverbs, which are unfamiliar and slow down comprehension.

- Use audiotapes and related worksheets to vary teaching methods. Each message should be no more than 5 minutes long. Patients respond favorably to sound effects, music, and a dialogue/story format.
- Get the reader actively involved with written materials. Include fill-in-the-blanks sections and ask the reader to apply the information concretely to his own situation.

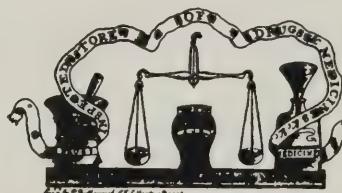
SPECIAL PULL-OUT SECTION

To assist you in promoting good communication about prescription and OTC medication, *The Maryland Pharmacist* is featuring a special pull-out section this month. Pages 15–18 can be removed from this issue and photocopied for bag stuffers or counter handouts. This material was developed for pharmacists by the National Council on Patient Information and Education who created "Talk About Prescriptions Month" in 1987.

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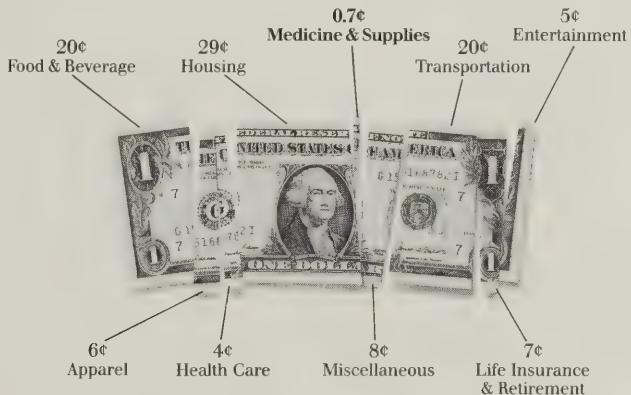
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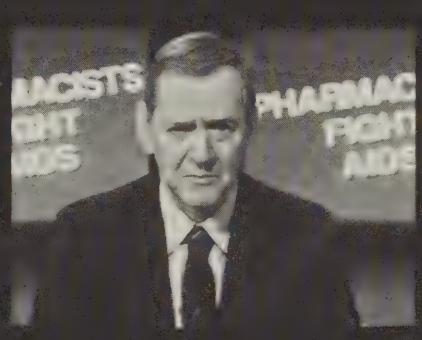
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Taxing Considerations About Lump Sum Distributions

by Gerald I. Klein
Consulting Group Associate
Shearson Lehman Hutton
36 S. Charles St., Suite 2201
Baltimore, Md. 21201

Ironically, the biggest payday for millions of retiring workers—the lump sum distribution from retirement, pension or profit-sharing plans—also presents their most important tax decision. How it's handled could well determine the quality of your lifestyle in the years ahead.

The funds in these various benefit plans have been growing tax-free while you were working, but the tax was only postponed until withdrawal or distribution of the funds—not forgiven. Now that you have, or are about to receive, possession of this large sum of money, you have three basic options:

Pay Taxes Now—You may wish to take advantage of certain favorable tax rates now, and then use or reinvest the remaining balance as you wish.

IRA Rollover—If you have no immediate need for the funds, you can deposit them in an IRA Rollover Account within 60 days of receipt of your distribution. This option will keep the full value of your retirement funds growing, while further deferring taxes.

Partial IRA Rollover—You may also elect to roll over only part of the distribution into an IRA; however, you must pay ordinary income taxes on the amount you keep.

As is always the case in an investment decision, the option you select will depend on your own financial situation and future needs. There is no right or wrong answer, but most financial consultants agree on a few general guidelines.

If you are over age 59 ½ and decide you need or want to keep the entire lump sum distribution, you can select either five-year or 10-year income averaging to reduce the tax rate. Five-year averaging generally will benefit investors with distributions in excess of \$500,000, while others will probably do better with 10-year averaging.

If you were 50 before January 1, 1986, but are under 59 ½ and participated in the plan for five or more years, you also can take advantage of five- or ten-year averaging due to a transitional rule in the Tax Reform Act of 1986. However, you will be subject to an additional 10 percent penalty tax (unless you are taking early retirement at age 55).

If you were under 50 before January 1, 1986, you will pay ordinary income tax and a 10 percent penalty tax. You can avoid the penalty by rolling over your lump sum distribution.

Another general rule is that the larger the amount you receive and the longer you can afford to set the money aside, the more advantageous an IRA Rollover is likely to be. The main reason is that the full amount of your distribution will continue to grow in the tax-deferred account, and you will pay taxes only when you withdraw funds.

By comparison, if you pay taxes on the lump sum now, you will have less money to reinvest, and subsequent income earned from those investments may be subject to ordinary income tax each year.

It is hardly surprising that more than two-thirds of all investors today opt for an IRA Rollover to defer taxes and keep the full amount of their retirement funds earning interest. Prior to the far-reaching Tax Reform Act of 1986, 10-year averaging was the method used by most lump sum recipients.

The serious investor about to receive a benefit plan distribution should carefully consider all available options, such as his or her near- and long-term financial plans and needs.

Deciding how to receive your retirement funds is not an easy decision. You should gather as much information as possible to learn how you can benefit from an IRA Rollover. A tax specialist can help you determine which tax formulas are most favorable for your situation.

After a lifetime of hard work to earn a comfortable retirement, it is more important now than ever to invest a little more of your time before you invest your retirement money.

Editor's note: *Gerald Klein is offering our readers a free booklet, "Making the Most of Your Lump Sum Distribution." To get your copy write to him at Shearson Lehman Hutton; 36 S. Charles St., Suite 2201; Baltimore, Md. 21201 or call at (301)837-5800.*

Communicate Before You Medicate.

whenever medicines are prescribed tell your health professionals about:

MEDICINES

Names of the medicines you are taking,
including nonprescription drugs.

PROBLEMS

Any problems you are having with your medicines
and any medicines to which you are allergic.

PREGNANCY

If you are or may be pregnant.



TALK ABOUT
PRESCRIPTIONS



National Council on Patient Information and Education
666 Eleventh Street, N.W., Suite 810, Washington, DC 20001, 202/347-6711



COMMUNICATE BEFORE YOU MEDICATE

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2. any problems you are having with your medicines;
3. medicines to which you are allergic;
4. if you are, or think you might be, pregnant.



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COMUNIQUESE ANTES DE TOMAR/RECTAR MEDICINAS

Cuando se le prescriban medicinas dígale a su proveedor de servicios de salud:

1. los nombres de todas las medicinas que esté tomando;
2. cualquier problema que esté teniendo con sus medicinas;
3. si usted tiene alguna alergia a alguna medicina;
4. si usted está o cree que puede estar embarazada.



REMEMBER TO TELL YOUR HEALTH PROFESSIONALS

My Doctor

Telephone Number

TALK ABOUT PRESCRIPTIONS MEDICATION MEMO

1 • The names of all prescription and nonprescription medicines you are taking.

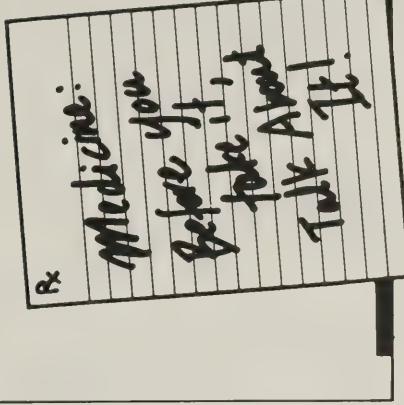
2 • The medicines to which you are allergic.

3 • If you are, or think you might be, pregnant.

My Pharmacist

Telephone Number

Provided by:



National Council on Patient Information and Education

MEDICATION MEMO

Check (✓) the small box next to the questions you want to ask your doctor, pharmacist, or other health professional. Keep this Medication Memo as a reminder and write down the answers.



What is the name of the drug and what is it supposed to do?

Name of medicine _____

Purpose of this medicine _____



How and when do I take it—and for how long?

Other instructions _____



Foods to avoid _____



Drinks to avoid _____



Medicines to avoid _____



Activities to avoid _____



Are there any side effects and what do I do if they occur?

Possible side effects _____

What to do if they occur? _____



Is there any written information available about the drug?

**REMEMBER TO TELL YOUR
HEALTH PROFESSIONALS**

My Doctor

Telephone Number

**TALK ABOUT
PRESCRIPTIONS
MEDICATION MEMO**

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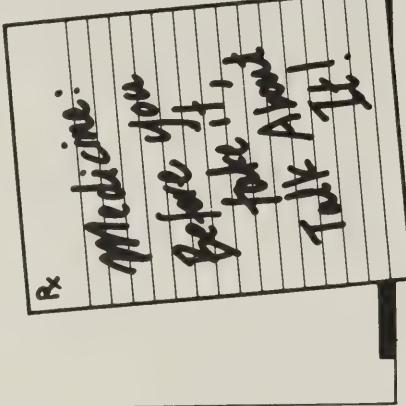
2. The medicines to which you are allergic.

3. If you are, or think you might be, pregnant.

My Pharmacist

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Activities to avoid



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Possible side effects



What to do if they occur?

Is there any written information available about the drug?

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Community Forum

This and That About Pharmacy

Leon Weiner, P.D.

NEWS IN BRIEF

Carl L. Heifetz, Ph.D. ('57) who has been with Warner Lambert Company in Ann Arbor, MI for more than 25 years, would like to hear from his classmates and friends. His address is 4608 Cottonwood Drive, Ann Arbor, MI 48108.

Alfred Schwartzman ('59) recently opened Kreis Pharmacy in west Baltimore. This store had been closed for about 6 months after the death of Herbert Schneyer, the previous owner. Schwartzman also owns Brookfield Pharmacy.

James Hanyok and his wife Karen became the parents of twin boys, David and Brian, on June 18, 1988. Jim ('81) works in cardiac research for Bristol Laboratories in Connecticut. They also have another son, Michael, who recently turned three. James received his B.S. from Maryland and his Pharm.D. from the University of Texas in 1984.

The Mark and Dorothy Levi family continue to make news! Dorothy ('70) will be the first woman pharmacist to be a member of the Maryland Board of Pharmacy. Mark ('70) is now involved with a computer pilot project to allow community pharmacists to confer with the faculty members of the School of Pharmacy. Their son, Michael, is the lucky boy who received the first baseball of the 1988 season thrown out by Gov. William Donald Schaefer. Mark and Dorothy were School of Pharmacy classmates and own the Medical Arts Pharmacy in Baltimore.

Ken Bauer, a member of the class of '89, is a nephew of Thomas Patrick ('55), president of the Alumni Association.

Sidney Zerwitz ('32) was the founder of the Pickwick Greenspring Senior Citizens Club in 1976. In 1979, he was a co-founder of the Pikesville Senior Citizen Club. Sid was the first president for both of these groups. He is the former owner of a pharmacy on Liberty Heights Avenue in Baltimore and the father of Warren Zerwitz ('61), who works for K Mart Pharmacy.

William A. Han ('49) has a lot to be proud of. Son Jeffrey ('71) is following in Dad's footsteps as a pharmacist. Other son Mark is one of the heroes for the Baltimore Thunder of the Major Indoor Lacrosse

League. In one game last season, Mark led the Thunder with four goals to victory over the New Jersey Saints, 16-15. In another game officials declared him MVP.

SICK CALL

Best wishes for a speedy recovery to Stacy Pass who had surgery at Sinai Hospital in early July. He is one of the owners of Chandler's Pharmacy in Landover Hills.

PHARMACY PASSINGS

Condolences to Irving and Carolyn Gleiman Shochet on the passing of their daughter, Ellen Lynn, on July 17, 1988. Irv ('48) is pharmacist-owner of Logan Drug in Dundalk.

Frank Engel, salesman for Loewy Drug for 36 years, died on June 3, 1988. Prior to this position, Frank worked for the White Cross Pharmaceutical House. He was also in the military service for five years. With Loewy, he called on mostly independent pharmacies. It was easy to tell that he enjoyed his association with pharmacy because Frank, a big man in stature, also had a big heart. He always had a smile on his face and a new joke or story to tell. He is survived by his wife Gertrude and two sons, Stuart, a surgeon in Rhode Island, and Raymond, an engineer in Pennsylvania.

Pharmacy Changes—July 1988

NEW PHARMACIES:

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Pharmacy
2809 Boston Street
Baltimore, MD 21231

Orem Medical
Corporation
1800 Belair Road
Benson, MD 21018

Safeway Pharmacy
#1418
Dares Beach Road
Prince Frederick, MD
20678

K Mart Pharmacy #3711
6716 Ritchie Highway
Glen Burnie, MD 21061

PHARMACY CLOSINGS:

Peyton Pharmacy
327 Main Street
Crisfield, MD 21817

Medical Center
Pharmacy
9380 Baltimore National
Pike
Ellicott City, MD 21043

Johns Hopkins Health Plan Pharmacy
2809 Boston Street
Baltimore, MD 21224

FOCUS ON A PHARMACY V.I.P.

Ralph Quarles (Howard '54) was a member of the Board of Pharmacy for 12 years from 1972 to 1984. He was president of the Board during 1978-1979. In 1979-1980, Dr. Quarles was president of the Baltimore Metropolitan Pharmaceutical Association. He received an honorary doctorate in Humane Letters in 1979 and a B.S. in Christian Education in 1988 from the Virginia Seminary Extension. Most recently, Dr. Quarles was the 1987-1988 president of the Maryland Pharmaceutical Society.

After graduating from pharmacy school, he worked for Robinson's Drug Store from 1954 until 1956 when he entered the army. At Fort McClellan, AL he continued his pharmacy career at the camp's pharmacy department. After leaving the service, he continued his work at Robinson's until 1970. With fellow pharmacist Willard Bulger, he opened Q & B Pharmacy on Pennsylvania Avenue in Baltimore. Meanwhile, Dr. Quarles also worked for the West Baltimore Community Health Center. After the closing of his store in 1983, he went to work for Rite Aid Pharmacy where he is presently employed.

On May 28, 1988 Dr. Quarles married Bernice Smith. He has three children from his first marriage. Ralph, Jr. is a tractor-trailer operator, Randall is a professional football player for the Baltimore Rams, and his only daughter, Daphne is a credit card authorizer for S.C.I.

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'Tween Scripts
By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.

Listening to Your Concerns



Any text on the subject will advise that communication is a two-way activity, consisting of listening as well as speaking. Practicing pharmacists often complain that we in the pharmaceutical industry fail to utilize either skill to an appreciable degree in our relationships with them.

In an attempt to address the issue of poor communications—in both directions—A. H. Robins' Pharmaceutical Division has established a Pharmacists Advisory Panel which will meet regularly to develop recommendations for policies and programs that will enable the division to better serve the profession. The panel consists of pharmacists employed by our company—both in Richmond and in the field—as well as practicing pharmacists from across the nation representing various practice settings who will be invited to join the panel as specific areas of interest are addressed.

One of the first activities of the Pharmacists Advisory Panel was the development and distribution of lapel pins and pocket protectors to assist pharmacists in publicizing to the public the profession's achievement of being named America's most respected profession. That program was an overwhelming success with over 100,000 of each item being distributed to date. The panel welcomes comment on such matters as the frequency and content of our representatives' calls on pharmacies, content of continuing education programs which A. H. Robins offers to pharmacists, our sales and return-goods policies, product information designed especially to suit pharmacists' needs, and consumer education materials for use by pharmacists.

If you have a concern or suggestion concerning how our company can better serve your needs, we urge you to communicate it to your A. H. Robins representative who will forward it to the panel for consideration. In the alternative, you may wish to write directly to me at the address below. You can be assured that careful consideration will be given to your concerns and suggestions.

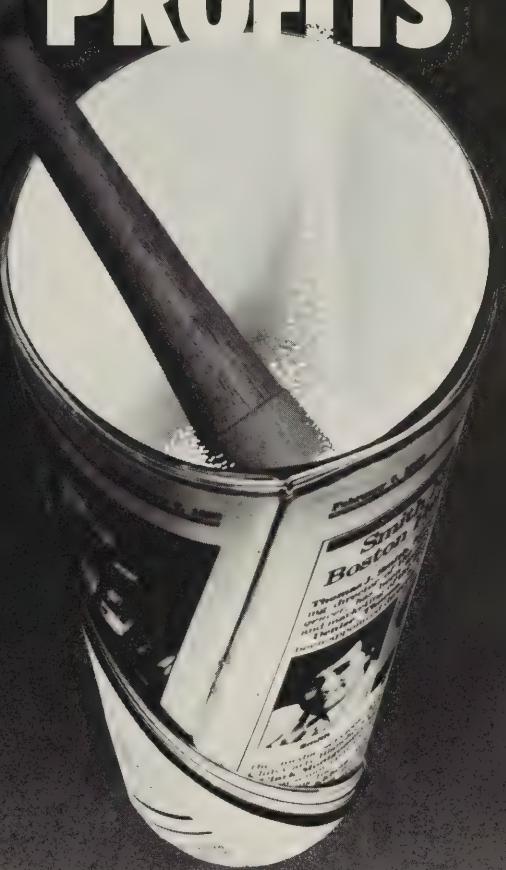
Communication is a two-way street, but in order to be effective you, too, must be involved in the equation, listening as well as speaking up with your concerns and suggestions.

May we hear from you?

Jake Miller
A-H-ROBINS

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During this past summer, pharmacists from across the United States and Puerto Rico were invited to enter a drawing to support pharmacy education. □ For every winning entry — 156 in all — Burroughs Wellcome Co. pledged to donate a \$500.00 scholarship to a pharmacy school and a matching \$500 grant to one of six national pharmacy associations of the winner's choice. □ To everyone who entered the drawing, thank you very much. And to the following winners, our most sincere congratulations:

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DICKINSON'S PHARMACY

by Jim Dickinson

Safe dispensing speeds. I asked my neighborhood pharmacist about it, and he immediately became uncomfortable. "It can happen to anyone," he said charitably. Then he changed the subject to something safer — politics.

Probably the most uncomfortable topic of pharmaceutical conversation since Galen, "accurate dispensing" is under the national spotlight.

Modern pharmacists work under intense pressure. Stripped to its basics, the process of dispensing is demanding enough, without the added complexities of such recent pressures as new interactions, new dosage forms, new routes of administration, new colors and shapes, new generic sources, and totally new entities.

Compress these considerations into the same spread of working hours per day, with the faster decision-speeds demanded by pharmacy computers, and you have a kind of pharmacy practice that "old doc" on the corner could hardly have dreamed about in Norman Rockwell's time.

Yet even he was apt to be defensive when the subject of dispensing accuracy came up.

Now we have the subject under national scrutiny because of allegations about the mail-order drug industry, and about one company in particular.

That company, Medco Containment Services Inc. (also known as National Rx Services), in defending itself against a prescription drug mix-up manslaughter charge in Idaho, has claimed a dispensing error rate of 0.0000006% (that's six zeros) of all the Rxs it has ever dispensed at its Las Vegas facility.

In contrast, it says that regular retail pharmacies have been measured as having a 5% error rate. The issue arises because of allegations that Medco places "enormous" pressure on its pharmacists, to the extent that dispensing speeds as high as 70-plus per hour have been claimed at the company. Medco denies this.

The Idaho court has been having a hard time dealing with this. As county prosecutor Craig Mosman charged in August, because of the company's habitual lying, who can believe what it says?

Medco, he told a local judge, has "made a systematic and deliberate practice of lying and covering up."

Mosman, a 29-year-old graduate of the local law school, withstood a blistering volley of accusations from four imported Medco attorneys in the case, which arises from the warfarin poisoning of 70-year-old Iris Hemmelman after she received a prednisone-labeled prescription from Medco's Las Vegas plant. The manslaughter charge, based on Medco's alleged "reckless disregard for human life" in its high-pressure, stressful dispensing of millions of Rxs a week, now goes to a jury trial in December.

During investigations prior to bringing the charge, Mosman said Medco seemed unable to tell the truth. When asked about whether Medco had ever had a dispensing mix-up, or ever been investigated over one, the company's main attorney, Robert D. Marotta had said "No."

But when immediately confronted with the fact of the Senate subcommittee hearing a year ago at which mix-ups were described, and at which he testified, Marotta said he had "forgotten" about that.

In addition, Mosman said, Marotta had falsely informed a Nevada investigator that Mrs. Hemmelman had been prescribed warfarin for "an exotic blood disorder" and had complained about symptoms of that drug before Medco had shipped any prescription to her. Marotta lied so that the investigator would come to the conclusion that he did come to—"case closed"—Mosman alleged.

An FDA investigation, and others of Medco that the company wants to be considered by the court had been mischaracterized by Medco, Mosman said. FDA simply concluded that it had no jurisdiction (not, as Medco claimed, that the company had done no wrong).

Further, a study by the University of Tennessee that Medco sought to be admitted as evidence of its dispensing accuracy was in fact only a public-opinion survey on mail-order pharmacy versus retail pharmacy and had nothing to do with Medco or the case.

At trial before a jury, Mosman intends to present evidence on what an accurate, safe dispensing speed should be.

He will seek to present unbiased witnesses who have studied this issue—which, because of its great sensitivity, is not one of the most-studied pharmacy issues there is.

One study he has scheduled for presentation is a 1983 *Drug Intelligence & Clinical Pharmacy* paper by Brock G. Guernsey et al of the University of Texas, indicating that there is a 90% chance of a pharmacist making one or more potentially serious dispensing errors per hour at the 30-prescriptions-per-hour rate that supposedly prevails at Medco's Las Vegas facility.

The study defined "potentially serious" as incorrect directions, incorrect drug, incorrect dosage formulation, incorrect drug strength, directions improperly

changed, pharmacist neglected to clarify order, or absent directions. The study was based on an audit of 9,394 Rx's filled in 12 days at an unnamed high-volume hospital outpatient pharmacy.

The study found a direct, linear correlation between errors and dispensing speed per hour, and it observed that most dispensing errors simply "are never detected." The authors recommended a dispensing speed limit of 120 prescriptions per shift—or about 16 per hour.

Whether Medco is ultimately found innocent or guilty, a growing number of authorities believe the time is now at hand when a national standard needs to be established for a safe dispensing speed.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Say “NO” to Financial Folly

September 12, 1988

Dear Fellow Pharmacists:

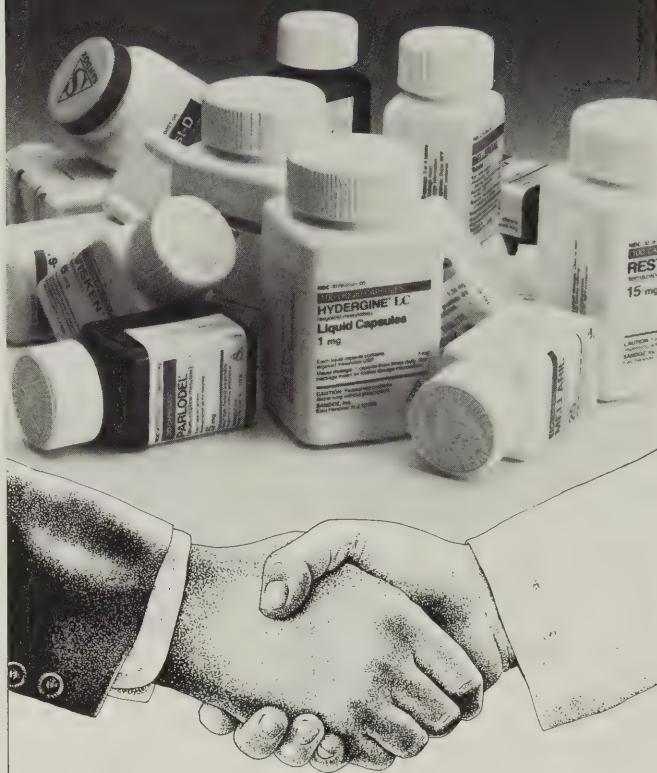
Let us not pander to the third-party payors. If we accept mark-downs to AWP as reimbursement for medicines under third-party plans, we cut our own throats.

Some of the chains are finally seeing the financial folly of these programs—they are saying "No." It behooves us to take a stand for the financial health of our profession. Just say "NO!"

**Leo Mallard, P.D.
Community Pharmacist
Chesapeake Beach, Maryland**

Editors Note: We invite all pharmacists to express their opinions in *The Maryland Pharmacist*. The purpose of our Commentary columns is to promote open discussion of the many issues facing pharmacists. All submitted letters and articles must be typewritten. The opinions expressed in *The Maryland Pharmacist* are those of the contributors and do not necessarily represent the policies and/or positions of the Maryland Pharmacists Association.

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Consult the package literature for prescribing information.

Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β-hemolytic streptococci).

Contraindication: Known allergy to cephalosporins

Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS

Administer cautiously to allergic patients

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colorectal flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Continue Ceclor in the event of allergic reactions to it
- Prolonged use may result in overgrowth of nonsusceptible organisms
- Positive direct Coombs' tests have been reported during treatment with cephalosporins
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in

moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.

• Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

• Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment

- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis in the above skin manifestations

accompanied by arthritis/arthralgia, and frequently, fever): 15%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome

• Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

• As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely

• Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertension, dizziness, and somnolence have been reported

• Other: eosinophilia, 2%; genital pruritis or vaginitis, less than 1%, and, rarely, thrombocytopenia

Abnormalities in laboratory results of uncertain etiology

• Slight elevations in hepatic enzymes

• Transient fluctuations in leukocyte count (especially in infants and children)

• Abnormal urinalysis; elevations in BUN or serum creatinine

• Positive direct Coombs' test

• False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly)

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The Annual SAMPA brunch and poolside fashion show was a great Convention success.



At Convention Dr. Smith presented a CIBA-GEIGY sponsored seminar on women's diseases and osteoporosis.



Past President Sam Lichter is chair of an ad-hoc MPhA committee reviewing physician dispensing for profit.



Attorney Joseph Kaufman has been invaluable to MPhA in its recent dealings with Blue Cross/Blue Shield.

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Continuing Education

Continuing Education Quiz

The Maryland Pharmacist October, 1988 OTC Calcium

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by January 1, 1989. A continuing education certificate for one contact hour (one credit) will be mailed to you within 30 days. Please type or print clearly.

Name _____

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Is this program used to meet your mandatory CE? [] Yes [] No

Did this article achieve its stated objectives? [] Yes [] No

How long did it take you to complete the program? _____ minutes

Correspondence Course Quiz

Calcium Supplements and Osteoporosis

1. The component of milk that forms a soluble compound with calcium and enhances its absorption is:
 - a. curds.
 - b. whey.
 - c. lactose.
 - d. renin.
2. Bone that is composed of compact, dense and solid tissue is referred to as:
 - a. matrix.
 - b. trabecular.
 - c. epiphyseal.
 - d. cortical.
3. The tissue type described in question #2 predominates over other forms in which of the following kinds of bone?
 - a. Long
 - b. Wrist
 - c. Vertebral
 - d. Hip
4. A consumer requesting information on the supplement with the highest amount of calcium per gram should be advised about:
 - a. calcium sulfate.
 - b. calcium gluconate.
 - c. calcium lactate.
 - d. calcium carbonate.
5. The type of seafood used to greatest extent to manufacture calcium supplements is:
 - a. clams.
 - b. lobsters.
 - c. oysters.
 - d. shrimp.
6. The leading hypothesis to explain the cause of osteoporosis is that bone resorption induces hypercalcemia which, in turn, decreases secretion of:
 - a. adrenocorticotropin.
 - b. calcitonin.
 - c. parathyroid hormone.
 - d. vitamin D.
7. Patients with which of the following diseases are most likely to experience pathological problems when taking calcium supplements?
 - a. Diabetes mellitus
 - b. Kidney stones
 - c. Myocardial infarction
 - d. Peptic ulcer disease
8. All of the following are true statements EXCEPT:
 - a. calcium is the most abundant mineral of the body.
 - b. an NIH study has shown that the diets of American women provide sufficient amounts of calcium.
 - c. calcium plays an important role in prevention and treatment of osteoporosis.
 - d. more than 90 percent of the body's store of calcium is deposited in bone.
9. The type of bone cell that synthesizes bone collagen and matrix is the:
 - a. osteoblast.
 - b. osteoclast.
10. Chronic use of thiazide diuretics is most likely to result in:
 - a. hypocalcemia.
 - b. hypercalcemia.

classified

FREE EMPLOYMENT placement service available from the MPhA—Call Beverly at (301) 727-0746.

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

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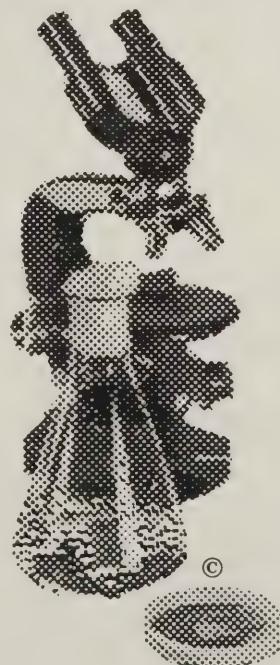
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| October 21 | MSHP Annual Seminary—Ocean City |
| November | Diabetes Awareness Month |
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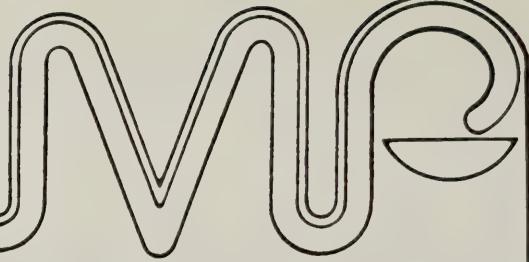
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Remembering Herman J. Bloom

As President of the MPhA, I would like to share with you some fond memories of a true friend of pharmacy, Herman Bloom who passed away this past month. Herman started many of us in the photofinishing and film business in our pharmacies. He guided and educated us and taught us how to promote this department through his company, Paramount Photo. Today, through his efforts, film customers still turn to the drug store as their first choice for photo work.

Herman took an active part in all phases of pharmacy and became a member of many of our organizations, including the MPhA, BMPA, and the Alumni Association. When something needed to be done, he could always be counted on to lend a hand. When the annual Pharmacists Banquet was planned, he distributed tickets for us. When the Alumni Banquet took place, there was Herman, year after year, rallying the pharmacists of the state to attend. It was because of his efforts that our Annual Theatre Party was a success. Herman attended all our annual conventions and was our official photographer until his retirement.

He was made an honorary frater of the AZO pharmacy fraternity. He was honorary president of the Alumni Association of the University of Maryland School of Pharmacy. Herman was honorary president of the Baltimore Metropolitan Pharmaceutical Association as well as the MPhA. He was also a member of the Rx-Club and helped plan their social events.

On a more personal note, Herman and I became very close friends more than 30 years ago while I was incapacitated and in bed for a year. He was a source of great encouragement on his many visits and a true help to my wife and family.

With the passing of Herman Bloom the pharmacists of our state feel as if we have lost one of our very own.

Elwin H. Alpern
Elwin Alpern, P.D.

President

Continuing Education

Beginning with this issue of *The Maryland Pharmacist*, our continuing education articles will enable you to earn 1 credit hour (0.1 CEU) towards fulfillment of your C.E. requirements. Read the article carefully and then complete the quiz that appears on page 30. Return the quiz to the MPhA offices as instructed on the quiz.

Correspondence Course

Counseling Consumers on Dry Mouth and OTC Artificial Saliva Products

by Thomas A. Gossel, R.Ph., Ph.D.

Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. define the causes of dry mouth and illustrate the medical dangers of a chronic condition; and
2. discuss methods of treating dry mouth with emphasis on OTC saliva substitutes.



Gossel



Wuest

Objectives

At the conclusion of this lesson, the participant will be able to:

1. choose the major functions that saliva normally provides;
2. define specific terms that relate to dry mouth and its treatment;
3. choose from a list of OTC products those appropriate for ameliorating or treating dry mouth;
4. exhibit knowledge of the pharmacology and therapeutics of OTC saliva substitute products; and
5. demonstrate an ability to correctly counsel consumers on dry mouth and its treatment.

Dry mouth (xerostomia, asialorrhea) is a common affliction associated with aging. Approximately 10 percent of persons over age 50, and 40 percent over 65 experience dry mouth. It is also a side effect of hundreds of drugs.

Many persons view it as an annoying nuisance of little pathologic concern. They accept it rather than seek professional assistance.

Chronic dry mouth is now considered a major health concern by the medical community. They realize that saliva is more than spittle to be casually swallowed or expectorated! A chronic deficiency can lead to morbid oral, dental and systemic pathology.

It is not adequate to simply recommend that affected persons chew gum, suck on hard candy or ice

chips, or rinse the mouth frequently with mouthwash, mineral oil or glycerin to remedy a dry mouth, without qualifying the recommendation. Relying solely on the use of such confections and products may actually exacerbate the patient's clinical problems.

This article explains the importance of saliva and discusses common causes of dry mouth. It elaborates on treatments, including the OTC saliva substitute products, and examines methods to overcome the affliction. Specific consumer information for pharmacists to convey to dry mouth sufferers is also provided.

Saliva

Saliva is a complex solution (Table 1). It is a mixture of secretions of the salivary glands composed of plasma, electrolytes and a variety of complex proteins including enzymes, antibodies and mucins (sugar-rich proteins). Approximately 1500 ml of saliva are normally secreted each day. There are two types: **serous**, produced by the parotid, sublingual and submaxillary glands, representing the larger volume; and **mucous**, produced by the buccal, lingual, labial and palatine glands, secreted in lesser quantity.

Parasympathetic (cholinergic) stimulation induces secretion of large amounts of both serous and mucous saliva. Sympathetic (adren-



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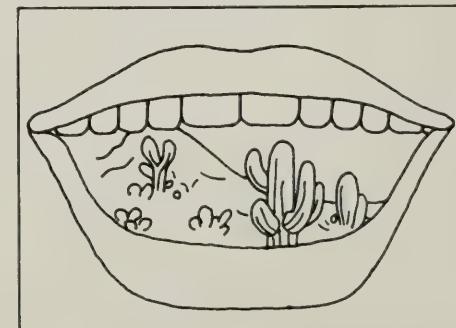


Table 1**Activity of Saliva**

| Function | Saliva Components |
|---------------------|--|
| Antibacterial | Lysozyme* |
| Buffering | Lactoperoxidase,* IgA** |
| Cleaning | Bicarbonate and phosphate |
| Lubrication | Physical flow |
| Physical protection | Glycoproteins, mucoids |
| Tooth integrity | Glycoproteins, mucoids Minerals Glycoprotein pellicle*** |

*Enzymes destructive to certain oral bacteria

**Antibody; inhibits attachment of oral streptococcus organisms to epithelial cells

***Thin, protective film covering

ergic) stimulation results in release of smaller amounts of a concentrated saliva by provoking vasoconstriction of blood vessels supplying the major salivary glands. A dry mouth results when the secretion of saliva is diminished or arrested.

The function of saliva is to maintain a healthy oral cavity. It moistens, cleanses, and lubricates the mucous membranes and teeth, and assists swallowing and digestion of food. It helps neutralize acids produced by bacteria that promote tooth decay.

Saliva is also antibacterial. It contains enzymes and antibodies which retard bacterial function and growth. Diminished salivary flow lowers the oral pH, encouraging an overgrowth of bacteria that thrive in an acidic medium. This in turn may result in an increased growth of microorganisms including *lactobacillus*, *Streptococcus mutans*, *Candida albicans* and *Actinomycetes naeslundii*. Much of the tooth and gum diseases that occur from chronic dry mouth result because of a loss of protective salivary electrolytes and immunoproteins.

Saliva also helps stimulate the taste buds. Taste sensations occur when substances are moistened and dissolved. Without saliva to moisten solid food, it would be bland and possibly tasteless.

Dry Mouth

Except on rare occasion, the onset of chronic dry mouth is insidious, developing slowly over a prolonged period. It may appear so slowly that the individual hardly notices it at first. Dry mouth is not a specific disease entity, but a symptom that re-

sults from a variety of underlying pathologies.

Dry mouth can be classed into one of two categories, based on its origin. **Functional dry mouth** is temporary and occurs when the salivary glands are relatively normal, but saliva flow is decreased or inadequate. Mouth breathing, nasal obstruction, stress and anxiety, and drug therapy may cause functional dry mouth.

Organic dry mouth is considered permanent, and commonly results from medical disorders such as Sjögren's syndrome. This is an autoimmune disorder of the salivary glands, with 70 percent of patients having serum antibodies against salivary duct antigens. It is associated with three major conditions: xerostomia, keratoconjunctivitis sicca (condition marked by corneal thickening and dryness, lacrimation and decreased visual acuity), and in one-half to two-thirds of patients, rheumatoid arthritis.

Organic dry mouth may also follow exposure of the oral tissues to radiation used to treat malignant neoplasms. Tables 2 and 3 summarize important causes of dry mouth.

Table 2**Causes of Dry Mouth**

| |
|--------------------------------------|
| Anemia (pernicious; iron deficiency) |
| Chronic anxiety |
| Dehydration |
| Depression |
| Diabetes |
| Fever |
| Gastrectomy; gastric resection |
| Irradiation of head and neck |
| Mouth breathing |
| Renal disease |
| Sjögren's syndrome |
| Smoking |
| Stress |
| Vagotomy |
| Natural process of aging |
| Drugs (see Table 3) |

Symptoms. Dry mouth is often described as a parched, burning sensation. Sufferers may initially complain of mild stomatitis (inflamed oral mucosa) or gingivitis (inflamed gums), and the oral mucosa becomes dehydrated and red. Fissures may appear. The tongue and lips may become dry, crack and bleed.

Degenerative changes appear in the creases of the tongue resulting in loss of taste perception. The affected individual may develop painful ulcerations of oral tissues leading to microbial invasion with resulting septicemia. Dry mouth also causes difficulty in chewing, speaking, swallowing and eating. Sore throat is persistent.

Dry mouth causes dental caries and periodontitis (inflammation of the supporting tissue of the teeth). Saliva is essential in removing food and debris from the teeth and gums. Without it, these may accumulate and cause dental and periodontal disease. Bad breath is very common.

Individuals who wear dentures are particularly troubled. Adequate sali-

Table 3**Drugs That Cause Dry Mouth**

| | |
|---------------------|-----------------------|
| Analgesics | Antipruritics |
| Antianxiety agents | Antipsychotics |
| Antiarrhythmics | Antispasmodics |
| Anticholinergics | Antituberculars |
| Anticonvulsants | Appetite suppressants |
| Antidepressants | CNS stimulants |
| Antiemetics | Decongestants |
| Antihistamines | Diuretics |
| Antihypertensives | Ganglionic blockers |
| Antineoplastics | Muscle relaxants |
| Antiparkinson drugs | Narcotic analgesics |

vation is required to assure denture stability and correct fit. Reduced lubrication and resultant tissue shrinkage associated with chronic dryness cause constant irritation to the tissues under the dentures. They soon become loose and do not fit well. Because food becomes trapped underneath, they require frequent cleaning, and mouth odor is severe.

Affected individuals wear their dentures for shorter periods each day since the gums are tender. Oral hygiene then suffers. This is soon compromised even more as caries develop in remaining teeth and periodontal disease appears. These people tend to switch to soft diets, usually with high carbohydrate content. This eventually leads to adverse effects on overall nutritional status.

Treatment

Treatment of chronic dry mouth is largely palliative. Measures are designed primarily to compensate for reduced salivary flow. For example, the affected individual may receive systemic treatment concurrently to correct the underlying cause of functional dry mouth. Alternatively, the person may receive parasympathetic stimulant (cholinomimetic) drugs (also called sialogogues), such as pilocarpine applied topically or bethanechol taken orally. While some individuals benefit from these pharmacologic tactics, most do not.

Parasympathetic stimulant drugs also cause their own adverse systemic effects. These include increased tearing and sweating, enhanced gastrointestinal secretions and laxation, increased urinary frequency, bradycardia and lethargy. Such symptoms generally contraindicate this chronic drug use in promoting salivation. However, some people obtain relief from topical administration of pilocarpine eye drops directly on the tongue and swished in their mouth, with little or no side effects.

Oftentimes the cause of functional dry mouth is drug related. Such iatrogenic (drug-induced) conditions may be managed adequately by decreasing the dosage of the offending agent, or changing the medication to an alternate drug that has less drying potential. For example, patients taking a tricyclic antidepressant may

switch from a strongly anticholinergic drug such as amitriptyline to a weakly anticholinergic such as desipramine.

Patients on antipsychotic drugs such as perphenazine (Trilafon[®]) or trifluoperazine (Stelazine[®]) that have strong extrapyramidal effects may need antiparkinson agents such as benztrapine (Cogentin[®]) or trihexyphenidyl (Artane[®]) to overcome these effects. These are anticholinergic drugs and, therefore, cause dryness. Switching the patient to alternate antipsychotic medication such as thioridazine (Mellaril[®]) or molindone (Molan[®]) that have less extrapyramidal action may solve the problem because they usually do not require secondary treatment with antiparkinson agents.

Dry mouth frequently diminishes in intensity after a week or two of antipsychotic or anticholinergic drug therapy, but can persist to some degree throughout treatment. Dry mouth is often the dominant anticholinergic adverse effect, remaining after other effects such as decreased sweating, difficult urination and blurred vision have been resolved.

Home Remedies. Various methods for increasing the moisture level in the mouth have been advocated. Affected individuals may sip water or thin soup; suck on ice chips, dill pickles, or hard, sugarless candies; chew sugarless gum; dissolve lozenges containing gelatin, glycerin, sucrose, and/or lemon in their mouth; or rinse their mouth with commercial mouthwashes or solutions of mouthwash mixed with equal volumes of mineral oil, fish oil, or glycerin. They may rinse their mouth with mixtures containing salt, diluted milk of magnesia, sodium bicarbonate, and hydrogen or carbamide peroxide to help debride the oral epithelium and relieve irritation. Another formulation composed of 2 percent citric acid in glycerin can increase salivary flow and is occasionally recommended.

These procedures may offer temporary relief of oral discomfort, but they must be employed frequently and are not always feasible. Most patients report very little long-term therapeutic benefit.

The effect from repeatedly rinsing the mouth with citric acid is not known, but it may be pathologic in

its own right. Salivary calcium can be chelated to citric acid. Some experts suggest that this may cause demineralization of teeth with increased caries production. And as stated before, none of these measures substitutes for naturally-produced saliva.

Some dentists recommend that patients carry a toothpick in their mouth. The presence of a foreign object in the mouth can stimulate saliva flow. Additionally, the person can use the toothpick adjunctively in oral hygiene procedures after eating.

OTC Saliva Substitutes

Although the OTC artificial saliva products (Table 4) are touted as saliva substitutes, they are actually OTC formulations whose components and properties are somewhat similar to natural saliva. Saliva substitutes can reduce some of the symptoms of xerostomia and provide greater patient comfort.

The products rely on thickening agents such as glycerin, carboxymethylcellulose and methylcellulose for proper viscosity. Various minerals, i.e., calcium and phosphorus which are normally found in saliva, are included. These may be important especially in remineralizing various lesions that are just beginning. Some manufacturers also incorporate fluoride into their formulations.

While commercially available products do not contain infection-fighting substances and digestive enzymes of natural saliva, artificial saliva products do mimic many of the protective properties of natural saliva. They can be recommended to patients with chronic dry mouth.

Some saliva substitutes contain methyl- or propylparaben as preservatives. Topically applied parabens are occasionally reported to cause hypersensitivity reactions. Individuals sensitive to parabens may choose to use the product (i.e., Salivart) that is packaged in a pressurized aerosol that maintains sterility without preservatives.

Some manufacturers employ sorbitol, a sugar alcohol, as a flavorant and humectant. Sorbitol is used in "sugarless" foods and confections, and FDA permits manufacturers to state that these items do not promote

Table 4

Representative OTC Saliva Substitute Products

| Product* | Manufacturer | Dosage Form |
|---------------------|--------------------------|---------------|
| Moi-Stir | Kingswood Laboratories | Solution |
| Moi-Stir Swabsticks | Kingswood Laboratories | Oral swabs |
| Moi-Stir 10 | Kingswood Laboratories | Pump spray |
| Orex | Young Dental | Pump spray |
| Saliva Substitute | Roxane | Squirt bottle |
| Salivart** | Westport Pharmaceuticals | Aerosol |
| Xero-Lube*** | Scherer Laboratories | Pump spray |

*Products contain electrolytes and sorbitol in carboxymethylcellulose

**Product does not contain parabens

***Same formulation as the product, VA-oralube, developed for the Veterans Administration, for exclusive use by veterans.

tooth decay. However, persons with diminished salivary flow who constantly use saliva substitute products containing sorbitol may experience an adverse effect. Sorbitol is readily fermented by the same oral microorganisms that induce dental caries (cavities). This can enhance caries formation.

The American Dental Association's Council on Dental Therapeutics has responded to the potential problem. The Council recommends a professionally-applied topical fluoride treatment program to overcome potential problems relating to sorbitol use.

Counseling Consumers

Individuals who complain of excessive dry mouth should be questioned about their use of prescription and nonprescription medications. If their dry mouth condition is severe enough to cause persistent discomfort, and an offending drug listed in one of the categories in Table 3 is being taken, the prescriber should be contacted or another OTC product should be recommended. A reduction in dosage, or alteration in drug prescribed, may be helpful. These individuals can also be instructed to follow the general guidelines outlined in Table 5.

Affected individuals should be urged to follow a balanced oral health care program. This includes scrupulous oral hygiene, regular dental examinations, and nutritional counseling.

Individuals should be cautioned to avoid relying regularly on confections that contain sucrose. The combination of sucrose and dry mouth can accelerate dental caries forma-

tion. Mouthwash products that contain detergents should be avoided. Detergents remove mucins from the oral tissues and worsen the condition. Products with high alcohol content likewise should be avoided since alcohol causes further drying.

OTC saliva substitute products possess therapeutic advantages over home remedies and mouthwashes for increasing the moisture level in the mouth. Saliva substitutes are palatable and have a relatively long du-

ration of action. They are safe and effective, and consumers can use them as frequently as necessary to keep their mouth moist. After swishing the dose throughout the mouth, the person should not drink excess fluids or rinse vigorously with other fluids.

Limited *in vitro* data indicate that fluoride along with calcium and phosphorus promotes remineralization of tooth surfaces. However, there is currently no clinical evidence that OTC saliva substitute products effectively induce sufficient remineralization to reduce caries formation.

Pharmacists can inform dentists of their willingness to stock artificial saliva products with emphasis on the specific brands these dentists prefer. Indicating that one is ready to discuss dry mouth problems with affected individuals, and will refer persons with severe or unresponsive cases and those with complications to a dentist for treatment will help establish a better relationship with dentists.

Table 5

Consumer Information for Dry Mouth

- Chewing sugarless gum or sucking on hard sugarless candy or ice chips may help make your mouth feel more comfortable.
- Drink at least 8 to 10 glassfuls of water each day. Take sips of additional fluids frequently throughout the day, and before, during and after each meal.
- Use a vaporizer or humidifier to add moisture to the air you breathe.
- If you smoke, reduce the frequency or stop smoking completely.
- Avoid beverages containing alcohol and caffeine, and highly-spiced bulky and dry foods, and condiments; moisten dry and coarse foods with a liquid before placing in your mouth.
- Try not to breathe through your mouth. If you are congested, ask your pharmacist or doctor to recommend a decongestant that will not aggravate your dry mouth further.
- Avoid using OTC mouthwash products that have high alcohol content or contain detergents. Your pharmacist can help you choose appropriate products.
- Ask your pharmacist to recommend an OTC saliva substitute product and use it as often as needed to keep your mouth moist. Carry a supply with you at all times.
- Apply a lip balm or petroleum jelly to your lips to help reduce drying and cracking.
- Although artificial saliva products make your mouth feel more comfortable, they are not a cure for your condition.
- Do not use any prescription or nonprescription medication without first checking with your pharmacist or doctor. Some may aggravate your dry mouth.
- Use a cold weather mask or cover your mouth and nose with a scarf when working or exercising outdoors in extremely cold weather.
- Follow your dentist's or doctor's advice on adhering to your nutritional and oral hygiene programs. Have regular dental examinations, preferably every 4 to 6 months or more often if necessary.



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Feature

This month *The Maryland Pharmacist* is focusing on biotechnology and the changing future of health care. This glossary will help you understand some of the terms used in the following articles. Also, be sure and use the patient handout on nuclear medicine procedures on page 26.

BIOTECHNOLOGY GLOSSARY

CELL FUSION: A process that joins two dissimilar cells to produce a new one with some properties of each.

CHIMERA: A cell or an entire animal or plant that contains genes from more than one source. For example, a yeast cell with mouse hemoglobin genes is a chimera.

CLONING OF DNA: A process by which a gene or gene fragment is isolated from one type of cell and introduced into cells of another type. The latter selectively produce additional copies of this gene and can be used to make the protein for which the new gene codes.

CLONING VECTOR: An agent, usually a plasmid (a small circle of DNA) or a virus, used to transfer genes from one cell type to another.

DNA: The abbreviation for deoxyribonucleic acid—the genetic material of all cells. DNA is composed of a chain of nitrogen-based subunits found in the chromosomes of the nucleus of a cell.

DNA LIBRARY: A collection of hundreds of gene-sized fragments of the total DNA of a cell. These fragments are produced by treating a cell's DNA with enzymes (special proteins) that cut the DNA at specific sites. At this stage of the process, the library is "uncataloged," that is, the meaning of each piece is unknown.

DNA PROBE: A small strand of DNA that is used to "fish" for its complement or matching strand (the other half of the DNA double helix).

GENE: A segment of DNA that gives a cell the instructions for making a particular protein or a shorter molecule called a polypeptide. DNA is made of subunits known as *nucleotides*; the average length of a gene is 1,000 nucleotides.

GENE MACHINE: An instrument that can chemically synthesize a gene from its small subunits, called nucleotides, according to programmed instructions.

GENE SPLICING: The attachment of a foreign gene to the DNA of another organism to yield a recombinant DNA molecule. Ultimately, the recombinant molecule is inserted into a host cell where it can be used to direct the synthesis of a protein new to that cell.

GENETIC ENGINEERING: The manipulation of the hereditary material of a cell. It includes the creation of specific mutations (changes), the introduction of genes from novel sources and the synthesis of artificial genes for insertion into a cell.

HYBRIDOMA: An artificially created cell made by fusing an antibody-producing white blood cell with an "immortal" cancer cell (one that produces unlimited generations of offspring). The resulting hybrid secretes a given type of pure antibody molecule and has an indefinite lifespan.

MONOCLONAL ANTIBODIES: Molecules of antibody that are pure—one type only, not a mixture—produced by a single variety of hybridoma cell.

PLASMID: A small circular, double-stranded piece of DNA found in some bacteria and yeasts. It reproduces as an independent unit separate from the cell's main DNA. Plasmids are used as cloning vectors to introduce new genes into these cells.

PROTEIN ENGINEERING: The design—by biochemical means—and production in host cells of proteins, including enzymes (biological catalysts) that are superior to their natural counterparts.

RECOMBINANT DNA: A piece of DNA that contains DNA sequences from more than one source.

RESTRICTION ENZYME: A biological catalyst isolated from bacteria that cuts double-stranded DNA at a specific sites on the molecules. Some 250 of these enzymes have been described, each with a different site of action.

RESTRICTION FRAGMENT: A short length of DNA obtained by exposing whole DNA to a restriction enzyme.

SHOT-GUNNING: The process of fragmenting the entire DNA of a cell and then randomly splicing the pieces to vectors for insertion into host cells. This process is used to clone a specific gene when that gene is more easily identified by its function or product in the new cell than by sorting out the DNA pieces in advance.

TRANSPOSON: A segment of DNA that has the ability to jump from one position on the chromosome to another and carry neighboring genes along with it. Transposons can be used as cloning vectors by splicing foreign genes to them.

Next Month . . .

Sleep

Triplet Rx Blanks

Women in Pharmacy

APPLICATIONS OF BIOTECHNOLOGY LIMITED ONLY BY IMAGINATION

Is biotechnology only a tool, or is it really a separate industry? Will biotechnology transform the agricultural and pharmaceutical industry? Or will it be absorbed into the more established companies? The answers to these questions will have a profound impact on the evolution of biotechnology.

Today biotechnology is a rapidly growing, highly competitive business, particularly in the United States, Europe and Japan. More than 100 American companies, most of them new, are developing pharmaceuticals using these techniques.

"Essentially, biotechnology is a tool used to produce products and probes for industry and other research enterprises," says Ralph E. Christoffersen, Ph.D., vice president of biotechnology and basic research support at Upjohn. "A very few biotechnology companies will become independent pharmaceutical companies, chemical companies or agricultural companies. Most will merge, go out of business or work under cooperative research contracts."

Some economic analysts predict that by 1995, \$120 billion worth of agricultural and health care products made in the U.S. by genetically altered cells will be sold annually. These projections are based on the expectation that accomplishments in the basic research laboratory can be scaled up to commercial production.

Several products already have been manufactured and approved for sale. Others are in various stages of testing. And literally hundreds are in the initial stages of development.

Already Available

Human insulin (Humulin, Eli Lilly): In 1982, a landmark year for biotechnology, the first genetically engineered product was approved for human use. Created by scientists at Genentech, Inc., human insulin is produced by bacteria that contain the human insulin gene spliced into their chromosomes. Clinical testing showed that Humulin is as safe and effective as animal insulins for the treatment of diabetes.

Human growth hormone (Protropin, Genentech): Growth hormone, formerly obtained in exceedingly small quantities from animal pituitary glands, can now

be made by genetically engineered bacteria. Human growth hormone (hGH) reached the market in October 1985, making it the second therapeutic hormone produced by biotechnology to be approved.

Synthetic hGH and its natural counterpart seem to have equal growth-promoting activity. HGH is intended for the treatment of children with pituitary dwarfism and other conditions that are related to growth hormone failure. Clinical research is still needed to determine what conditions will respond to hormone supplements and whether the hormone will affect the final height or just accelerate the growth rate. These questions remain unanswered because, until now, there had not been enough GH for clinical studies.

Human Interferon (Roferon, Hoffman-LaRoche; Intron, Schering-Plough): In June 1986, interferon became the third therapeutic agent produced by biotechnology to be granted FDA approval. Two companies were simultaneously granted the right to market this drug for use against a rare form of cancer called hairy cell leukemia.

Interferons are multifunctional proteins that may be effective in treating some cancers and viral infections. There are at least seven types of interferon. Alpha interferon is the type approved for commercial sale. Produced by cells infected with viruses, interferons exert a protective effect on neighboring cells against the same or other viruses. Interferon was formerly obtainable only in small quantities from specially cultured human cells. But today, the genes for several kinds of human interferon have been cloned in yeast and bacteria. At least a half dozen American, Japanese and Swiss biotechnology companies are commercially producing interferons, which are now in clinical trials.

Scientists in England report that intra-nasal infusion of interferon can protect against colds caused by coronavirus. Interferon also is being tested as an adjunct in the treatment of AIDS and in genital warts and herpes — major public health problems.

Monoclonal antibodies: Monoclonal antibodies are single, pure antibodies produced in unlimited quantities by joining "immortal" cancer cells and antibody-producing white blood cells. A monoclonal antibody binds

to and attacks a specific type of antigen (a general term for a substance foreign to the body).

As diagnostic tests of the future, monoclonals are already appearing in great profusion. Some are replacing traditional tests for infections such as meningitis and venereal disease. Today's most common sexually transmitted disease is caused by **Chlamydia trachomatis**, a small bacterium that until recently was difficult and expensive to detect. It is a leading factor in female infertility and can be fatal to a fetus. A monoclonal antibody test kit for this infection makes it possible to screen women quickly and easily for chlamydial infection.

Other monoclonal antibodies can be used to diagnose immunological deficiency diseases by identifying and counting populations of specialized white blood cells. Patients with AIDS (acquired immune deficiency syndrome), for instance, have a deficiency of helper T cells, a type of white blood cell that can only be detected with the aid of special monoclonal antibodies.

Monoclonal antibody test kits are rapidly reaching the market. And monoclonal disease-fighting agents, which help to direct drugs to target sites, also are on the horizon. There's an acute need for new agents to more specifically combat cancers and viral infections. Monoclonals may fill some of these gaps.

In the Works: Clinical Trials in Progress

Interleukin-2: This protein molecule is produced by some white blood cells when they are stimulated by foreign invaders. It promotes the multiplication and activation of other white blood cells to combat the invasion. Interleukin-2 can now be churned out by genetically engineered bacteria in amounts that make it possible to test its effects in immunodeficiency diseases such as AIDS.

Tissue plasminogen activator: Heart attacks can be caused by small clots that form in the coronary blood vessels, depriving the heart muscle of needed oxygen. Patients recovering from such attacks are treated with clot-dissolving enzymes and anti-coagulant therapy. Bleeding in other parts of the body can be a side effect because some drugs interfere with clot formation in general. An enzyme called tissue plasminogen activator has recently been produced in genetically engineered mammalian cells. This substance, usually made by the capillary cells, acts only at the site of the clot. Thus, it does not have the undesirable side effect of causing excessive bleeding as do other anti-coagulant agents.

Human renin: Renin is an enzyme produced in the kidney which facilitates the production of angiotensin II. Angiotensin II is several times more potent than adrenalin in elevating blood pressure and heart rate. Excessive angiotensin may be responsible for the development of a disorder called **malignant hypertension**—the most lethal form of high blood pressure.

Until now, it has not been possible to acquire enough pure renin to fully characterize the enzyme. But Kazuo Murakami, M.D., professor of molecular biology at Tsukuba University in Japan, has isolated and cloned the gene for human renin. Using recombinant DNA techniques, this cloned gene was instrumental in producing large quantities of renin. The goal is to find or design agents that will block renin and provide effective treatment for the hypertension it causes.

DNA probes: Small pieces of DNA that are identical to part of all of a gene can be used to search a cell for viral infection or genetic defects.

Often, a cell may be infected with a latent virus and give no detectable sign. An individual may not even produce antibodies to show that his or her cells are infected. Probes with copies of only parts of the viral DNA may be used to hunt for viral genes.

One viral disease, cytomegalovirus infection, is life-threatening to newborns and to patients whose immune systems are suppressed (such as those undergoing chemotherapy for cancer). Traditional methods of detecting the virus took as long as two months. With a DNA probe, the virus can potentially be detected within 24 hours.

Recently, a DNA segment linked to the gene for Huntington's chorea was identified. This fatal, inherited, nervous system disease does not appear until mid-life, after the individual may have had children. Using a DNA probe for the Huntington's gene will allow a person to know whether he or she is carrying the deadly gene before making a reproductive decision.

Recombinant vaccines: Lederle Laboratories and Molecular Genetics, Inc., have succeeded in cloning a gene from herpes simplex virus into E. coli bacteria. The bacteria produce a herpes protein in use experimentally to immunize against both oral and genital herpes. A rabies virus protein for use in a vaccine has similarly been cloned.

Swine pseudorabies, a herpes virus disease, is a major killer of piglets. Upjohn is exploring both a synthetic and a live recombinant pseudorabies vaccine as well as a diagnostic test that can differentiate vaccinated pigs from carriers of the virus. Since farmers cannot sell pigs that test positive for pseudorabies, a diagnostic test that can distinguish vaccinated animals from those actually having pseudorabies is essential.

Prospects for Agriculture

Applications of gene manipulation for the improvement of food crops and animals lag behind those for health care.

Until now, agricultural researchers have relied on more traditional methods of animal breeding and plant hybridization, which have been remarkably successful in increasing the world's food supply. However, they have limitations, and the field is gearing up to use some of the newer techniques, with breakthroughs imminent.

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Animal husbandry: Cattle may grow larger and faster and produce more milk if the genetically engineered **bovine somatotropin** (BST) works. (See photo enclosed.) The gene for BST was cloned by scientists at Genentech and is being produced by Monsanto. It is expected to increase the meat and milk production of cattle herds.

Animals, too, will benefit from feed additives, such as amino acids, vitamins and proteins of microbial origin that will be produced by biotechnology. New techniques for animal breeding include test-tube fertilization and the transplantation of embryos into surrogate mothers to increase the number of offspring produced by prize cattle.

New crops through biotechnology: The "new" biotechnology for agricultural use is still being developed. Scientists have yet to get any agriculturally important new genes to produce their products in a host plant, but they have successfully transferred foreign genes into some plants and expressed them. These genes have come from bacteria, mice and other plants.

A Ti plasmid (small ring of DNA) normally found in the bacterium *Agrobacterium tumefaciens*—the agent of crown gall disease of plants—is being used to insert new genes into plants. Foreign genes are spliced into Ti plasmids that have been altered so they no longer cause disease. When placed back into the bacterium, the genetically engineered plasmid can infect a wide range of higher plant cells and, of course, carry with it the desired gene.

It should one day be possible to splice in many genes—for instances, ones that improve photosynthesis, that allow plants to use nitrogen from the air in place of fertilizer or that makes plants resistant to certain diseases and herbicides. Once an individual plant cell has been altered in this way, it will be induced to differentiate and grow into an entire mature plant.

Plant tissue culture—growing groups of plant cells in laboratory dishes—is being used to develop more productive food crops and trees. Protoplast fusion, a technique that combines cells of two unrelated plants, is being explored as a technique for producing new varieties of important crops. Individual cells, stripped of their cell walls, are treated with a chemical that makes the cells fuse together. The hybrids are then grown with hormones that promote development into mature plants. Plant breeders are thus trying to develop pest-resistant, fungus-resistant, hardier crops.

Other Industrial Applications

In the future, industrial chemicals, petrochemicals, enzymes and food additives will be produced partly or solely by microorganisms engineered specifically for these purposes. Some new developments are highlighted here.

Enzymes: The natural source of rennin, an enzyme used in cheese making, is calf stomach. The uncertainty of the calf supply has spurred a search for new sources.

A rennin enzyme, isolated from bacteria, is even better suited to large-scale cheese production.

Using protein engineering, the basic rennin enzyme was produced to yield a catalyst that speeds the aging process, yet makes the cheese taste as if it had aged naturally. The Japanese were first to clone the natural calf rennin gene in bacteria, followed shortly by several Americans. Cheddar cheese experts agree that cheese produced using the cloned rennin tastes like natural cheddar and has the same texture.

The conversion of cellulose waste material into sugar and liquid fuel (ethanol) is a major industrial goal involving the new biotechnology. Cellulose, made out of pure glucose (sugar) subunits, is a key component of wood, plants and paper scrap. Fungi, found on the forest floor, have enzymes that break down cellulose.

Scientists at Cornell University have cloned a fungus cellulose (enzyme) gene in *E. coli*. As a result, the bacteria now produce an enzyme that converts cellulose to glucose at a temperature of 65°C. (Carrying out the conversion at this high temperature prevents contamination by other bacteria.) The resulting glucose can be used in food or further fermented by microorganisms to yield ethanol.

The Business of Biotechnology

Biotechnology is research-driven. Many of the revolutionary developments that are bearing fruit today had their origins in university research laboratories. In a few cases, university professors who recognized the potential applications of biotechnology joined with financial backers to form new companies.

Other biotechnology companies were founded by entrepreneurs who formed companies and named professors to their boards. At first small, the new industry appeared to have such promise that all sorts of arrangements were born.

If discoveries in basic research are to reach the public, three steps are necessary: large scale production, approval of the product by various regulatory agencies and, finally, marketing.

In most cases, the pioneer companies do not have the needed capital or experience to handle all three steps. Established pharmaceutical firms have considerable advantages in this regard.

With bovine growth hormone, for example, a major difficulty is getting the microbes to grow en masse and churn out large quantities of the hormone. As major producers of antibiotics, which also come from microbes, many pharmaceutical houses have tackled—and overcome—such problems for years.

Thus, many small biotechnology companies opt to sell the rights to their discoveries to older, well-established chemical and pharmaceutical houses with proven expertise and resources. Also, a number of large companies now have their own biotechnology research departments and/or cooperative agreements with small biotechnology companies or universities.

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Summary.

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Administer cautiously to allergic patients.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in

moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.

● Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

● Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include

● Gastrointestinal (mostly diarrhea): 2.5%

● Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.

● Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthritis; and frequently, fever]: 1.5%, usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

● Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

● As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

● Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertension, dizziness, and somnolence have been reported.

● Other: eosinophilia, 2%; genital pruritis or vaginitis, less than 1%, and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

● Slight elevations in hepatic enzymes

● Transient fluctuations in leukocyte count (especially in infants and children).

● Abnormal urinalysis; elevations in BUN or serum creatinine

● Positive direct Coombs' test

● False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clintest® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly). (061088L)

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ETHICAL ISSUES IN BIOTECHNOLOGY

By 1974, several groups of genetic researchers were able to transfer genes from one organism into another.

Realizing that the new technique had potential for both harm and good, 11 scientists called for a voluntary moratorium on certain kinds of recombinant DNA experiments until they could fully analyze their possible impact.

Never in the history of science had there been such an event: scientists calling a halt to their own work to discuss its implications *before* their discoveries were widely implemented.

The scientists held an international conference in 1975 in Asilomar, Calif., to discuss a course of action. From that meeting, voluntary guidelines were drafted to:

- (1) restrict the kinds of recombinants (cross-species genetic mixes) that could be made;
- (2) define safety procedures to prevent new organisms from escaping the laboratory; and
- (3) attempt to isolate a safe bacterial host in which to clone (reproduce) the genes—one that could not survive outside the laboratory.

They also recommended that, in the United States, the National Institutes of Health (NIH) form a committee to establish guidelines for all recombinant DNA work supported by federal funds. This resulted in the creation of the Recombinant Advisory Committee (RAC) appointed by the NIH. Researchers were to submit their proposals for the committee's review before work could begin. Industrial researchers voluntarily followed suit.

Controversy Occurred When Scientists Went Public

The Asilomar meeting stirred controversy among experts in the public sector. Objections were voiced against experiments that would create "new life forms."

Some feared that organisms might escape the lab and upset the ecological balance. Others worried that these so-called "new creatures" might be harmful to humans. One hypothetical scenario concerned bacteria engineered to make insulin: Scientists were uncertain whether these might wreak havoc on sugar metabolism if they accidentally entered an individual's digestive system. Or whether new toxin-producing bacteria might contaminate water supplies.

Even the most strict containment procedures didn't satisfy certain critics. Some municipalities, for example, tried to halt all recombinant DNA research at universities and industrial facilities within their boundaries.

Another concern was that humans were tampering with the natural process of evolution in an unpredictable and unprecedented way by creating new life forms. But scientists soon found that genetic recombination "also occurs in nature—and on a scale that is very much greater than what we do in the laboratory," says Bernard D. Davis, M.D., emeritus professor of bacterial physiology at Harvard Medical School in Boston. Not only does DNA from one species of microorganism transfer genes to another in the normal course of sexual reproduction, but when a person consumes a steak dinner, some DNA from the beef finds its way into the genes of the intestinal bacteria.

At first, the absence of any prior experience with genetic engineering led scientists to consider catastrophic scenarios as possibilities. When knowledge grew, so did the realization that genetic engineering does not necessarily represent a new magnitude of danger in scientific research. "The kinds of things they were planning to do were not dangerous experiments that would open a Pandora's box," Dr. Davis adds. So, they were permitted under strict supervision of RAC. Today, because it is known that most recombinant DNA experiments pose no special risks, most recombinant DNA experiments are exempt from RAC supervision.

Who Regulates Genetic Engineering?

The Recombinant Advisory Committee of the NIH has the legal mandate to oversee genetic engineering research that is supported with U.S. government funds. The Biotechnology Science Coordinating Committee, representing the scientific, legal and public sector, reviews proposals to protect the public interest and promote U.S. technology. Since 1979, RAC also has been reviewing voluntarily submitted industry proposals. Industry has voluntarily complied with these guidelines. Industry proposals are studied in closed session to protect proprietary interests. Further, universities and drug companies have local committees that oversee laboratories conducting recombinant research.

The United States Environmental Protection Agency (EPA) regulates any release of recombinant DNA into the environment.

Clarifying the Role of Universities in Biotechnology

The foundations of biotechnology were laid by academic researchers in university setting. But when the business potential of the new discoveries became apparent, questions arose as to the proper role of universities and their scientists in commercial ventures. The position of Columbia University in New York City typifies the stance many universities have taken to resolve controversies and avoid conflicts of interest.

"The university is not in the business of commercial development of discoveries made in basic research," says Kathleen Mullinix, Ph.D., vice-provost of Columbia. "That role is best left to the private sector which has the resources to do it. It is in the public interest for the discoveries made in universities to get out of the lab notebooks and into commercial development. Public dollars have funded the research, and the public should benefit from it."

Columbia, like many universities, has patented inventions made by its faculty and has sold licenses for development and marketing to private industry. The university uses the proceeds to support further research—a particular boon in this time of shrinking federal support.

Some Questions Persist

Environmental impact: Although humans have bred animals and hybridized crops—a form of genetic engineering—for thousands of years, the introduction of products of the new genetic technology has met some opposition.

"Many of the field tests planned by universities and corporations in California have been held up by either court injunction or voluntary restraint until the environmental impact issues can be resolved," says Fred Betz, biologist in the office of pesticide programs at EPA.

Gene therapy: It is theoretically possible to introduce genes into cells of mammals, including those of humans, whether they be cells in culture, fertilized embryos or somatic (body) cells. Scientists so far have successfully transferred the human hemoglobin and growth hormone genes into mouse embryos. These human genes produced their human proteins in mice and also were inherited by the mice's offspring.

It may be feasible in the future to correct genetic defects by inserting a normal gene into cells to replace a defective, disease-causing one. The most likely diseases to be treated in this manner are those controlled by a single gene. Attempts to correct genetic defects in humans have yet to be sanctioned in the U.S.

Two forms of gene therapy, however, are envisaged. *Somatic cell repair* would correct the genes in select body cells, but not be transmitted to the next generation. *Germ-line repair* would rectify a defect in eggs or sperm, and the correction would be passed to offspring.

The U.S. Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was convened in 1980 to study the potential impact of the new medical technologies. Composed of scientists, physicians, lawyers and experts in ethics and public affairs, it considered the social and moral issues of human genetic engineering. The commission's findings, *Splicing Life: A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings*, were released in 1982. They concluded that the problems associated with gene therapy were similar to those associated with other therapies with the exception of germ-line repair. Since future generations would be affected by such procedures, the commission urged great caution. In general, it recommended that a permanent panel be formed to continue to review the short- and long-term effects of genetic technologies on humans.

Weapons for biological warfare: The 1984 meeting of the American Association for the Advancement of Science (AAAS) heard warnings of the misuse of biotechnology in the production of biological weapons. Currently, the U.S. Department of Defense is conducting and supporting recombinant DNA research aimed at developing vaccines for infectious diseases such as anthrax, malaria, dengue fever, encephalitis, trypanosomiasis and Rift Valley Fever. The intent is claimed to be defensive. The Department of Defense also monitors developments in the field for possible military applications. Hence, the specter of using genetic engineering to make new lethal agents cheaply was a concern of participants at the meeting.

The 1972 treaty between the U.S. and Soviet Union banning the development, production and stockpiling of biological weapons needs to be updated, according to some experts, to include defensive weapons as well as a credible verification provision. Some AAAS panelists argued that research in the area of defenses against biological weapons is politically destabilizing as well as fruitless.

Any aggressor, they said, could employ biotechnology to make a limitless variety of biological agents for military applications. To minimize such a risk, the U.S. has an export curb on shipments of cultures and materials that could be used by hostile nations to manufacture biological weapons.

Patents for New Life Forms

A U.S. patent is a governmental grant giving an inventor the right to exclude others from making, using or selling the invention or discovery in the U.S. for 17 years after the date the patent is issued. Patents encourage innovation and investment in the development of that innovation. Private industry cannot afford to undertake product development without patent protection.

Continued on page 18.



Greg Wood speaks at October 31 Press Conference on PCS Plan 354. MPhA and BMPA officers attended.



After the press conference, Wood elaborated on the pharmacists' position to labor representatives.



Rich Hollander, WBAL-TV news reporter, covered the BMPA press conference. The pharmacists position was aired on several of the day's newscasts.



Len Goldberg of Dolfield's Pharmacy and representatives of the Affiliated State, County and Municipal Employees Union.

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A historic U.S. Supreme Court ruling in 1980 recognized the patentability of genetically modified microorganisms. Other patents soon were granted, and many more—for processes or products of genetic engineering—are pending.

Some university scientists no longer feel free to discuss their work informally with colleagues for fear of losing potentially patentable inventions or commercially valuable research. Furthermore, scientists must apply for patents before or soon after they publish their discoveries. If a scientist does not apply for a patent within a year after publishing a report of a new development, the development becomes unpatentable.

Most universities now have legal staffs to protect their scientists' inventions by obtaining patents. The scientists are then free to discuss their work, and the university can sell licenses to private firms. The net effect is to slow scientific peer recognition somewhat, but it allows a continuing flow of information and exchange of ideas that are vital traditions in science.

New Issues Arise: Does Everyone Have the Right to be Tall?

Genetically engineered human growth hormone (hGH) is now available in large quantities. This allows for large-scale clinical studies to be performed and for the treatment of hormone-related growth deficiency.

But what about its use to increase stature artificially in "normally" short children, those at the lower end of the height chart? Some studies suggest a societal bias against short people. It is reflected in such things as economic status, career advancement and personality development. And some parents, hoping to have tall children who will have careers in modeling or athletics, are seeking out physicians to treat their children with growth hormone. A few experts already have voiced concerns about possible medical and social consequences of such height enhancement.

"Neither the effectiveness nor the risks of giving hGH to children who have no deficiency are known," says Stephen Burstein, M.D., Ph.D., assistant professor of pediatric endocrinology at the Pritzker School of Medicine of the University of Chicago. "I do not feel at the present time that there is any role for GH therapy except in an investigational setting for the treatment of children with extreme short stature—the kind that might impose physical limitations on the child's life."

This one issue highlights the kinds of concerns that will have to be faced as a result of the revolution in biotechnology.

Overview

Discoveries in basic biotechnological research over the past decade have launched yet another technological revolution. The tools of biotechnology will be used to answer some fundamental questions about biological processes. They also will allow scientists to alter the

genetic endowment of plants and animals, including humans. These changes have the potential to modify the environment, reduce human dependence on the uncertainties of nature and improve the quality of life.

As with all great technological advances, biotechnology will affect the social environment, raise ethical questions and pose yet unknown risks. However, the public is better informed and more involved than ever before. Public agencies continue to monitor developments in the field in order to balance the needs of the citizenry with the advancement of science and technology.

RECOMBINANT DNA TIMELINE

- 1871— Discovery of DNA in sperm of trout from Rhine River.
- 1941— Discovery of Transposons by McClintock.
- 1943— DNA shown to be capable of altering the genetic heredity of bacteria.
- 1953— Double helix DNA structure proposed by Watson and Crick.
- 1956— DNA genetic messages conveyed by sequence of base pairs.
- 1958— DNA replication involves separation of double helix strands.
- 1959— RNA polymerase discovered.
- 1960— Messenger RNA discovered.
- 1966— Establishment of the genetic code.
- 1967— DNA ligase discovered.
- 1972— First recombinant DNA molecules synthesized.
- 1973— Bacterial cloning of any gene shown possible (in principle).
- 1974— Discovery by Kohler and Milstein of hybridoma technique for synthesis of monoclonal antibodies.
- 1975— Asilomar Conference urges adoption of guidelines regulating recombinant DNA experimentation.
- 1976— Release of NIH Guidelines (N.Y. Times urges no Nobel Prizes for rDNA research).
- 1977— Genentech formed.
- 1979— General relaxation of NIH Guidelines.
- 1980— Construction of first industrial rDNA plant (insulin production).
- 1980— Cohen/Boyer DNA Cloning process patent awarded to Stanford University.
- 1981— Lab strains of *E. coli* and yeast are exempted from NIH Guidelines.
- 1982— Genentech/Lily approval to market recombinant insulin.
- 1985— FDA approval of Genentech's application to sell human growth factor.
- 1986— Two companies win FDA approval to market recombinant interferon.

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Commentary

Dickinson's Pharmacy

Jim Dickinson

NARD's little black box. As you look at the lengthening line of various transaction boxes on your bench top, you might be pardoned for inwardly grimacing at the thought of another one.

But please wait. You could be facing the prospect of sweeping them all out of your pharmacy for ever. All but one, that is—the one we're about to discuss here.

Described by Harry Soza in the September *NARD Journal*, the "box to end all boxes" is actually any box that meets powerful specifications developed for NARD's national PSAO, RxNet, by Preferred Solutions Inc., of San Jose, California. So far, only Verifone's Tranz 330 meets these specifications, but others will surely follow.

RxNet's specifications are the only ones yet written for prescription claims processing, bank cards, Discover and others.

"We're *not* in the black box business per se," RxNet CEO Martin J. Lambert emphasizes; the national PSAO did not want to get caught up in hardware costs, or sales and rentals of hardware. The RxNet system for electronic transaction boxes is actually a telephone master switch operated under RxNet contract by Atlanta's BuyPass The System, Inc.

This switch, accessible by any RxNet-certified box, will at last "level the playing field" between independents, chains, and other pharmacies, Lambert believes. It will do this by putting all of them into the same medium of exchange—the box.

The concept is amazingly simple, and revolutionary. Instead of thinking about transactions as exclusionary (do you accept Master Card, 3PM, Paid, etc.?—tough if you don't), this on-line, single-box system fosters inclusionary thinking by offering equal access to all, including, of course, the bank and other cards.

Logged by phone at RxNet's switch in Atlanta, each vendor's transaction charges are figured automatically, according to what the individual pharmacy has signed up for through their PSAO—and no matter what that is, the single, certified box will do it.

Prescription selling prices, of course, remain where they always were—competitively negotiable, without artificial system exclusions. But now you won't be locked out simply because you can't get in.

You have probably seen this new technology work already in restaurants and some gas stations—no matter what card you have, a single machine reads it and verifies the card's status and credit limit by making a phone call. That call is routed through the master switch or translator service (which gets a fraction of a dollar fee for its work) to the appropriate account.

The all-American spirit of competition is preserved, as it is supposed to be, among the active participants in the system, but competition is eliminated or bypassed where it is destructive to those participants. That is, the old competition among different systems' transmission protocols (baud rates, stop bits, etc.) that used to exclude other systems, now is brought to the party through translator switches, creating the new currency of modern trade, as usable by all as is the dollar.

RxNet's new system will apply the same principles to any pharmacy—chain, supermarket, whatever—and the transaction extracts its royalties, fees and charges (i.e., to the bank, the carrier, the "switch" processor, the phone company, the pharmacy, the PSAO, etc.) as it moves electronically from the box through the BuyPass The System's RxNet switch to its destination. Charges are automatically deducted from your monthly reimbursement check from the PSAO.

NARD has been moved by marketplace realities—the latest of which, of course, is the new Medicare drug legislation—beyond the old exclusionary strategy of trying to lock competitors out of your pharmacy. Now competitors must be included, to the extent of using the same electronic "currency" with which all may compete fairly, without hindrance, and on a "level playing field."

The technology that has brought this about is mind-boggling. With fiber-optics and space satellites, credits and debits, Rx eligibilities and ID numbers flash in microseconds through data banks accessed by a dial pad on a single box the size of your hand.

For magnetic striped cards, or the newer laser cards, the process does not even require button-pushing in order to be activated and "on line" for each new transaction. Unstriped cards may be read by their embossed codes, with button-pushing, and cardboard IDs or no IDs can be handled by maximum button-pushing—but all transactions access the same on-line verification technology.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Once in active mode a mini-screen on the face of the box flashes prompts for each new step of the transaction—third party payor, group number, Rx number, refill number, days' supply, NDC labeler number, etc., etc. . . .

Because RxNet's system is friendly to all plans—the only limitation being the pharmacy/PSAO contract terms and status—its installation in every pharmacy is only a matter of time. Your biggest problem is likely to

be telling which box is truly RxNet-certified and which isn't (RxNet is planning to set up an 800 number for instant verifications before you buy or rent a box).

Nobody wants to think about it in such bleak terms, but there will surely come a time when the only pharmacies without "the box" (RxNet-certified) will be those that are out of business.

Did you ever hear someone say pharmacists will never get their act together long enough to survive?

TriPLICATE RX'S An Opinion

Phil Karn, P.D.

The MPhA should actively support a three part controlled substances prescription program. In the 33 years that I have been a retail pharmacist, one of my biggest frustrations has been the lack of an effective way of deciding if a narcotic prescription should be dispensed. How can we as individuals guard against the expert who steals or forges prescriptions; against the shopper who goes to three different doctors and to four other pharmacies; or against the doctor who, for whatever reason, is too generous in his narcotic prescribing? The aggravation and wasted time and effort of the pharmacist are secondary to the inconvenience, embarrassment, and possibly pain, visited on the innocent but suspicious looking patient.

The outright fraudulent prescription is not the only problem. The level of usage is in some ways philosophical. Dispensers and prescribers are always subject to second guessing by authorities. To state that this is the professional responsibility of the pharmacist is to state

the obvious. But with the modern technology available to us, pharmacists should have the benefit of information about what is happening outside our pharmacies and beyond our control.

If the Division of Drug Control monitored *every* C-II prescription in a *timely* and automatic fashion then we could be alerted to a problem as soon as it develops. Peer review then becomes effective.

The argument that the paperwork load would be too great for the pharmacist is far exaggerated. The extra time and effort required of the pharmacist is trivial. There is only one extra thing that the pharmacist must do. After filling a controlled prescription, he places the duplicate copy in a pre-addressed envelope and mails that batch once a month to the Division of Drug Control. With modern computer analysis the Division can spot problems and the prescriber, the dispenser, and the patient will know that any abuse will be quickly uncovered.

Editors Note: Dr. Karn is currently researching pharmacist attitudes about triplicate prescriptions in other states. We will feature his findings in an upcoming issue of The Maryland Pharmacist.

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Institutional Forum

Understanding Anti-anxiety Medications: A New Era in Biological Psychiatry Unfolds

by Steven M. Paul, M.D.
Chief, Clinical Neuroscience Branch
National Institute of Mental Health
Bethesda, Maryland

Research over the past few years has brought scientists closer to understanding the neurobiological basis of anxiety. With this increased understanding has come new knowledge about how the benzodiazepines work.

They are the drugs of choice for many of the estimated 13 million Americans with anxiety disorders. A fuller understanding of their role in the biological processes of anxiety promises still more accurate diagnosis and better treatment of anxiety and other conditions for which this class of minor tranquilizers is indicated.

Anxiety as a clinical condition is closely related to fear, but it is more often based on an exaggerated or imaginary perception of a threat.

The underlying biological changes, though, are similar, and this similarity has helped us understand the complex interplay between the brain and the heart, stomach, blood vessels and other organs under the control of the peripheral nervous system.

Anxiety, for instance, can cause a rapid heart beat, stomach upset and episodes of high blood pressure.

In times of danger or stress the brain needs to tell the body that something alarming is happening or is about to happen. So it sends out "excitatory" messages through the peripheral nervous system in what has been called the fight or flight response. The prime receivers are the adrenal glands located above the kidneys, which produce and release the hormone epinephrine, also known as adrenalin.

A sudden release of adrenalin and cortisol from the adrenal glands will produce many of the bodily symptoms associated with anxiety: increased heart rate, cardiac arrhythmia, rapid breathing and elevated blood pressure.

Acute stress also causes the central nervous system to increase its production, release and metabolism of norepinephrine (noradrenalin). In monkeys, for example, blood plasma concentrations of the breakdown products of norepinephrine and epinephrine are elevated following periods of arousal or vigilance brought on when a minute area of the brain called the locus ceruleus is stimulated, either by a mild electrical charge or by drugs. The monkeys behave as if they were

anxious and exhibit increased heart rate, blood pressure and respiration.

Searching for a Biological Basis of Anxiety

Composed of only a few thousand cells located near the brain stem, the locus ceruleus contains the nuclei of most of the brain cells that produce norepinephrine (noradrenalin). Five major tracts of noradrenergic nerve fibers extend from the locus ceruleus to targets throughout the brain—all areas thought to be involved in the emotional states of arousal, including alarm and fear. Some scientists believe that activation of the locus ceruleus triggers panic attacks in people who suffer from panic disorder.

In what is described as the "noradrenergic hypothesis" of anxiety, several groups of researchers have gathered data to suggest that overactivity in the locus ceruleus is associated with some of the clinical signs and symptoms of anxiety. If so, reducing the firing rate of nerve cells in this brain region (inhibiting central noradrenergic activity) may help to control anxiety.

On the other hand, drugs that increase locus ceruleus activity typically produce anxiety and increase the turnover of norepinephrine in healthy human volunteers, just as such drugs do in the monkeys mentioned earlier.

Altering the Level of Anxiety by Modulating Central Nervous System Activity

People who drink five to ten cups of coffee in a day may react as if they had a generalized anxiety disorder. They may be restless, nervous, insomniac and agitated, and suffer from stomach upsets and cardiac rhythm abnormalities.

Caffeine produces these effects by antagonizing a naturally occurring and potent central nervous system depressant (neurotransmitter) called adenosine, causing locus ceruleus nerve cells to increase their activity (firing rate).

Conversely, benzodiazepines help inhibit locus ceruleus activity. They augment the effects of GABA

(gamma-aminobutyric acid), an inhibitory neurotransmitter.

GABA is an amino acid believed to be present in about 30 percent of the synapses in the brain. (Synapses are the minute junctions or gaps between a nerve terminal and another neuron.) GABA binds to neural recognition sites, or receptors, which are located only on nerve cells.

When a benzodiazepine such as diazepam (Valium, Roche) or alprazolam (Xanax, Upjohn) enters the brain, it binds to a benzodiazepine receptor that is structurally associated with the GABA receptor and produces a sedative behavioral effect. Interestingly, the benzodiazepines do not have a biological impact on their own but must interact with the GABA system to produce their result.

Many studies have now confirmed that the benzodiazepines reduce anxiety, in part, through a biochemical action involving augmentation of the inhibitory actions of the brain's GABA system. This action makes the neuronal membrane more permeable to chloride ions, which flow into the neurons and bring about a less excitable state.

Further complicating the picture, the nonbenzodiazepine anti-anxiety agent buspirone (BuSpar, Mead Johnson) appears to increase locus ceruleus activity yet has anti-anxiety properties. Thus the noradrenergic hypothesis does not explain the entire anxiety story.

Benzodiazepines in the Central Control of Anxiety

Doctors have used benzodiazepines since 1960. In the United States alone they write about 100 million prescriptions for them each year.

The benzodiazepines are effective at much lower doses than other minor tranquilizers (barbiturates, chloral hydrate). This implies that the benzodiazepines are more specific in reducing anxiety than are most—if not all—of these other medication.

Following their administration, benzodiazepines bind to cells throughout the body but are preferentially absorbed by fatty tissues, such as the brain. Benzodiazepine receptors are also present in the central nervous system.

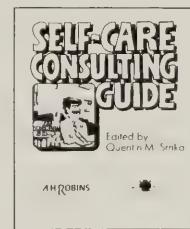
Enhancing GABA activity with benzodiazepines does more than reduce anxiety. It also relaxes muscles and protects against seizures. So researchers are now investigating whether the benzodiazepines' anti-anxiety action can be separated from these other effects. Also under investigation is the possibility that the body itself may manufacture its own anxiety-specific inhibitors. Progress in either area could sharply improve treatment of the biological malfunctions central to the anxiety disorders.

The image shows the front cover of a book titled "Tween Scripts" in large, stylized script letters. Below the title, the author is listed as "By Jake Miller, Pharmacist Manager, Professional Relations A.H. Robins Company, Inc.". To the right of the text is a black and white caricature portrait of a man with short hair, wearing a suit and tie, smiling.

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The time is now for the pharmacist to expand his or her role as self-care consultant. The reasons are numerous. First, there is a need for self-care consulting services, and this need will expand as health care costs spiral and as our population ages. Second, surveys show that pharmacists are our nation's most trusted health professionals—ideally positioned to provide more comprehensive health care services. And third, self-care consulting may provide an opportunity for many pharmacists to survive and prosper in an economy that is becoming more and more competitive.

The A. H. Robins Company, in cooperation with the American College of Apothecaries, is distributing *Self-Care Consulting Guide* as a service to the pharmacy profession: This 183-page book focuses on ways pharmacists can expand their interactions with consumers in a cost-effective manner. The *Guide* is edited by Quentin Srnka, an outspoken proponent of pharmacy who coined the term, "self-care consultant." Contributors to the *Guide* include pharmacists, a physician, and an attorney who espouse the self-care philosophy.

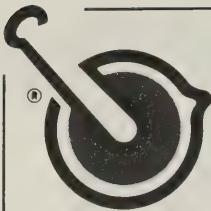


Self-Care Consulting Guide is available to all pharmacists on a complimentary basis. The *Guide* is excellent reading and should motivate pharmacists to give serious thought to expanding their involvement in activities related to patron self-care. Included with each copy are questions which cover the content of each of the nine sections. Pharmacists who complete and return the answer card and achieve a grade of at least 70 will receive 2.0 CEU's (20 contact hours) of continuing education credit.

To receive your free personal copy of the *Guide*, you need only to write to me at the address below, asking for a copy of the *Self-Care Consulting Guide*. I believe that you will find it to be a highly-readable, useful addition to your pharmaceutical library.

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Community Forums

This and That About Pharmacy

Leon Weiner, P.D.

IN THE NEWS . . .

Frank R. McGinity ('72) of McGinity Pharmacy in East Baltimore showed how the double edge of the sword worked when he wrote the following letter to his community newspaper. It appeared in the August 11, 1988 edition of *The Guide*.

Editor, *The Guide*:

Several of my General Motors patients have gotten their new prescription cards. The cards require generic substitution.

General Motors is running an advertisement which tells us to buy genuine GM parts and calls the substitutes "imitation."

G.M. tells me as a professional to substitute drugs and tells me as a consumer not to substitute for G.M.

They may think we look dumb, but we're not stupid

PHARMACY PASSINGS . . .

Condolences to Harry Prostic ('35) on the passing of his wife Sonia (nee Cooper) on August 16, 1988.

Samuel C. Cohen ('14) died on August 26, 1988 at the age of 93. After graduation, Sam served in the Army during World War I working as a pharmacist at Fort McHenry and other posts in the U.S.. In 1918, he opened the Franklin Pharmacy at the corner of Franklin and Greene Streets in Baltimore City and operated it for 37 years. After selling this business in 1955, Sam worked for Liberty Pharmacy, Professional Pharmacy on Liberty Road and other drug stores until two years ago. He was a member of the Baltimore Veteran Drugists Association.

Royal Smith ('65—Ohio Northern) passed away suddenly on August 26, 1988. After graduation Royal moved to the Washington, D.C. area to work for Peoples Drug Inc. In the early 1970's he bought Harris Pharmacy from Mickey Friedman and a few years later opened the Pratt Professional Pharmacy. At the time of his death, he owned Harris Pharmacy and the Southwest Professional Pharmacy. He is survived by his wife, Melva, and one child, Ryan, age three. Royal was 46 years old.

PHARMACY CHANGES—August 1988

NEW PHARMACIES:

Institutional Pharmacy Services
740 Ashburton Street
Baltimore, MD 21216

Home Center Pharmacy
154 W. Main Street
Hancock, MD 21750

Institutional Pharmacy Services
301 St. Paul Street
Baltimore, MD 21202

Cystic Fibrosis Pharmacy
11420 Rockville Pike, #10
Rockville, MD 20852

PHARMACY CLOSINGS:

Rite Aid #3819
6471 Marlboro Pike
District Heights, MD 20747

PHARMACY NAME CHANGES:

Harbor Hospital Center Pharmacy
3001 S. Hanover Street
Baltimore, MD 21230
(Formerly South Baltimore General Hospital Pharmacy)

calendar



- November 10—MSHP Monthly Meeting
November 13—CE Program, The Cancer Patient
November 18—School of Pharmacy Phonathon
December 1—MSHP Monthly Meeting
January 18–25—MPhA Trip to Aruba
February 5—MPhA Mid Year Meeting
March 12—BMPA Annual Banquet/Dance

FACT SHEET: NUCLEAR MEDICINE PROCEDURES

What Are Diagnostic Nuclear Medicine Procedures?

There are two types of nuclear medicine procedures:

1. those which use radioactive tracers to analyze blood and urine samples, and
2. those which are injected, ingested or inhaled into the body to image a specific organ or analyze the function of a specific organ system. These procedures, referred to as nuclear imaging, have provided a whole new approach to medical diagnosis.

How Does Nuclear Imaging Work?

Small amounts of radioactive pharmaceuticals, called radiopharmaceuticals, are injected into an arm vein (or administered through ingestion or inhalation). The nuclear medicine principle is based on the fact that a radioactive chemical has properties identical to those in the body, which "trace" the radioactivity through specific organs of the body. The amount of radioactivity at different points within the patient's body, or in body fluids, is examined by radiation detectors. Using these detectors, medical personnel can measure the amount of radioactivity within parts of organs as well as within the whole organ.

How Does Nuclear Imaging Help?

The images can show altered functions or lesions, revealing, in most instances, where biochemical processes are occurring normally and where they are occurring too slowly or too quickly.

In Which Areas Of The Body Is Nuclear Imaging A Successful Diagnostic Tool?

The thyroid, liver, kidneys, brain, lungs, bones and heart. Some specific conditions that can be diagnosed

through nuclear imaging include hyperthyroidism, hypothyroidism, renal disease, lesions of the liver, pulmonary embolism, heart disease, and stroke. In heart attack victims, for example, nuclear medicine procedures can help identify which patients are at great risk of suffering a second attack and which are likely to develop angina pectoris. These procedures can also help assess the effectiveness of prescribed drugs in treating disease, rather than relying only on the patient's symptoms.

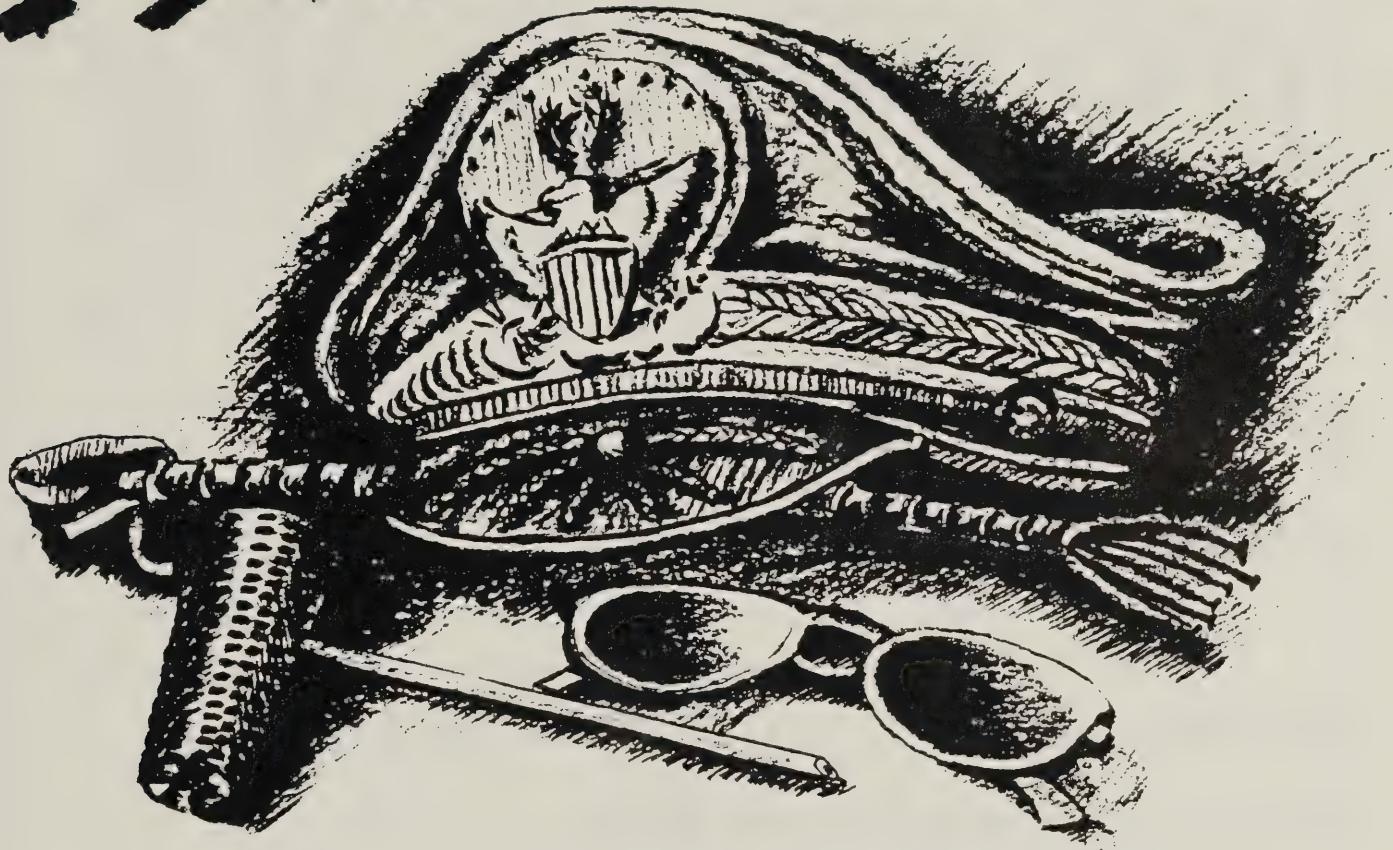
What's Ahead For Nuclear Medicine?

Scientists are now investigating if nuclear medicine procedures can help in the diagnosis of mental illness, Alzheimer's disease, brain tumors, epilepsy and cancer.

Is Radiation Safe?

The fact is that natural radiation exposure is a daily reality, through external sources, such as cosmic rays, and internal sources, such as food and water. Furthermore, we all have naturally-occurring radioactive atoms within our bodies, such as potassium 40, for example. Since everybody responds differently to the environment, it is not a simple task to identify exactly how much radiation constitutes a "safe" dose. What is known is that nuclear medicine procedures often provide fast and safe diagnosis. Furthermore, very small doses of radiation are used for each nuclear medicine procedure—so small in fact that the patient is usually exposed to less radiation than in a routine chest x-ray. Most radiopharmaceuticals are quickly eliminated from the body—usually within hours, and rarely for more than a few days.

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Continuing Education Quiz

The Maryland Pharmacist November, 1988

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by February 1, 1989. A continuing education certificate for one contact hour (one credit) will be mailed to you within 30 days. Please type or print clearly.

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Dry Mouth and OTC Artificial Saliva Products

1. The sugar-rich proteins contained in saliva are best described as being:
 - a. antibodies.
 - b. enzymes.
 - c. mucins.
 - d. plasma.
2. Which of the following drugs would most likely be beneficial in alleviating dry mouth?
 - a. Anticholinergics
 - b. Beta-adrenergic blockers
 - c. Cholinomimetics
 - d. Sympathomimetics
3. When saliva production is diminished, overgrowth of bacteria is encouraged due to the resulting:
 - a. lower pH in the mouth.
 - b. higher pH in the mouth.
4. The saliva component that is LEAST likely to function as an antibacterial agent is:
 - a. lysozyme.
 - b. IgA.
 - c. lactoperoxidase.
 - d. glycoprotein.
5. The term that best describes dry mouth is:
 - a. agyria.
 - b. hyposalivemia.
 - c. sialogogue.
 - d. xerostomia.
6. The OTC saliva substitute that is marketed in an aerosol dosage form is:
 - a. Moi-Stir.
 - b. Orex.
 - c. Salivart.
 - d. Xero-Lube.
7. The type of dry mouth that is temporary, and results from decreased or inadequate saliva flow as occurs with mouth breathing, stress and drug therapy is referred to as:
 - a. atropic dry mouth.
 - b. functional dry mouth.
 - c. hyperplastic dry mouth.
 - d. organic dry mouth.
8. Serous saliva is produced by which of the following types of salivary glands?
 - a. Buccal
 - b. Palatine
 - c. Labial
 - d. Parotid
9. Which of the following substances is LEAST likely to be an ingredient in OTC saliva substitutes?
 - a. Alcohol
 - b. Carboxymethylcellulose
 - c. Electrolytes
 - d. Sorbitol
10. Which of the following actions on the autonomic nervous system causes the secretion of smaller amounts of a concentrated saliva resulting in dry mouth?
 - a. Parasympathetic stimulation
 - b. Sympathetic stimulation

classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

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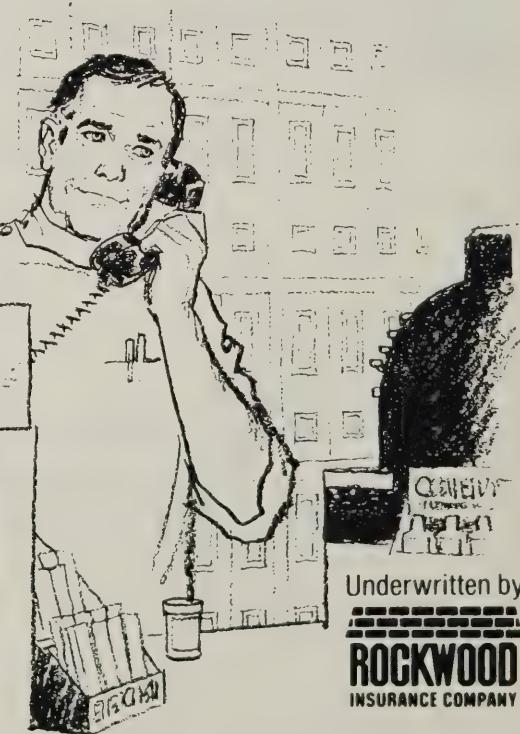
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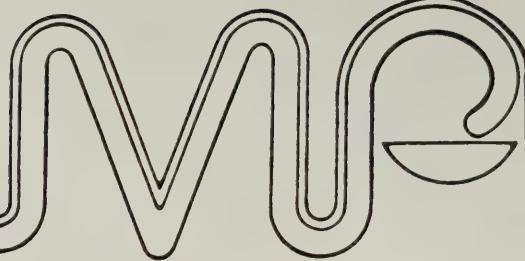
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It's Not Too Late Guest Commentary

With the enactment of Title 19, the Medicaid bill, in 1967, President Johnson ushered in an era of governmental and third-party involvement that has changed the face of pharmacy. The concept of third-party prescription drug programs originated that same year as the result of an agreement between Ford and the UAW.

From this point on, pharmacists had their destiny placed in the hands of MBA's whose knowledge of our profession was as limited as it was short-sighted. Ignoring the fact that they were dealing with a profession, these morosophs proceeded to dictate how we were to practice. We were relegated to the same class as electricians, plumbers, and cleaners—government vendors. Pharmacy was forced to offer the well-to-do the same price that the government extracts from us in the name of the indigent. Because of federal anti-trust pharmacies are prevented from effectively negotiating price with the insurance companies. Pharmacies are dealt with on a one-by-one basis and with a take-it-or-leave-it proposition.

For too long, pharmacy shunned the political arena. Law was for lawyers, not health professionals. To be involved in political affairs was taboo. Pharmacy has slowly awakened to find that our profession was completely unknown in the halls of the legislature. MPhA founded a political action committee and enlisted the aid of a professional lobbyist. I might add that we were the last of all the health professionals to hire a lobbyist.

This year, pharmacy will be heard in Annapolis and in Washington. We have scheduled a Legislative Breakfast on January 25, 1988 at the Annapolis Radisson and we expect a large attendance, including Governor Schaefer and Lieutenant Governor Steinberg. We have raised a strong PAC war chest thanks to you. We have a state-wide network of legislators and friends to aid us in the preservation of our professional status. Maryland pharmacy declares its right to the highest form of citizen participation in a democratic society—the right to petition our government and right to redress.

Nathaniel Futerl, P.D.

Chairman

MPhA Legislative Committee

SOME THINGS ARE BETTER LEFT ALONE.

Not all medications are so easily interchangeable.

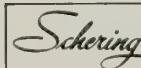
Some operate within narrow therapeutic windows, so that even minor differences in release characteristics or reproducibility of blood levels can lead to significant differences in clinical response.

Switching, once a patient is controlled on a particular sustained release theophylline formulation, can result in undesirable side effects or symptom breakthrough. You should be aware of these risks, as well as your state's restrictions concerning substitution.

At Schering, we believe there's no substitute for therapeutic success. That's why we also believe there's no substitute for THEO-DUR.

Please see next page for brief summary of prescribing information.

THEO-DUR®
(theophylline anhydrous)
Sustained Action Tablets
There's no substitute for success.



Helping America breathe easier.

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THEO-DUR®

THEOPHYLLINE (Anhydrous) Sustained Action Tablets

INDICATIONS THEO-DUR is indicated for relief and/or prevention of symptoms of asthma and for reversible bronchospasm associated with chronic bronchitis and emphysema.

CONTRAINDICATIONS THEO-DUR is contraindicated in individuals who have shown hypersensitivity to theophylline or any of the tablet components.

WARNINGS Status asthmaticus should be considered a medical emergency and is defined as that degree of bronchospasm which is not rapidly responsive to usual doses of conventional bronchodilators. Optimal therapy for such patients frequently requires both *additional medication*, parenterally administered, and *close monitoring*, preferably in an intensive care setting.

Although increasing the dose of theophylline may bring about relief, such treatment may be associated with toxicity. The likelihood of such toxicity developing increases significantly when the serum theophylline concentration exceeds 20 mcg/ml. Therefore, determination of serum theophylline levels is recommended to assure maximal benefit without excessive risk.

Serum levels above 20 mcg/ml are rarely found after appropriate administration of recommended doses. However, in individuals in whom the theophylline plasma clearance is reduced for *any reason*, even conventional doses may result in increased serum levels and potential toxicity. Reduced theophylline clearance has been documented in the following readily identifiable groups: 1) patients with impaired renal or liver function; 2) patients over 55 years of age, particularly males and those with chronic lung disease; 3) those with cardiac failure from any cause; 4) neonates, and 5) those patients taking certain drugs (macrolide antibiotics and cimetidine). Decreased clearance of theophylline may be associated with either influenza immunization or active infection with influenza.

Reduction of dosage and laboratory monitoring is especially appropriate in the above individuals. Less serious signs of theophylline toxicity (i.e., nausea and restlessness) may occur frequently when initiating therapy, but are usually transient, when such signs are persistent during maintenance therapy, they are often associated with serum concentrations above 20 mcg/ml. Unfortunately, however, serious side effects such as ventricular arrhythmias, convulsions or even death may appear as the first sign of toxicity without any previous warning. Stated differently, *serious toxicity is not reliably preceded by less severe side effects*.

Many patients who require theophylline may exhibit tachycardia due to their underlying disease process so that the cause/effect relationship to elevated serum theophylline concentrations may not be appreciated.

Theophylline products may cause dysrhythmia and/or worsen pre-existing arrhythmias and any significant change in rate and/or rhythm warrants monitoring and further investigation.

The occurrence of arrhythmias and sudden death (with histological evidence of necrosis of the myocardium) has been recorded in laboratory animals (mini-pigs, rodents and dogs) when theophylline and beta agonists were administered concomitantly, although not when either was administered alone. The significance of these findings when applied to human usage is currently unknown.

PRECAUTIONS THEO-DUR TABLETS SHOULD NOT BE CHEWED OR CRUSHED

General Theophylline half-life is shorter in smokers than in non-smokers. Therefore, smokers may require larger or more frequent doses. Morphine and curare should be used with caution in patients with airway obstruction as they may suppress respiration and stimulate histamine release. Alternative drugs should be used when possible. Theophylline should not be administered concurrently with other xanthine medications. Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, in the elderly (especially males) and in neonates. In particular, great caution should be used in giving theophylline to patients with congestive heart failure. Frequently, such patients have markedly prolonged theophylline serum levels with theophylline persisting in serum for long periods following discontinuation of the drug. Individuals who are rapid metabolizers of theophylline, such as the young, smokers, and some non-smoking adults, may not be suitable candidates for once-daily dosing. These individuals will generally need to be dosed at 12 hour or sometimes 8 hour intervals. Such patients may exhibit symptoms of bronchospasm near the end of a dosing interval, or may have wider peak-to-trough differences than desired.

Use theophylline cautiously in patients with history of peptic ulcer. Theophylline may occasionally act as a local irritant to the G.I. tract although gastrointestinal symptoms are more commonly centrally mediated and associated with serum drug concentrations over 20 mcg/ml.

Information for Patients The physician should reinforce the importance of taking only the prescribed dose and time interval between doses. THEO-DUR tablets should not be chewed or crushed. When dosing THEO-DUR on a once daily (q24h) basis, tablets should be taken whole and not split. As with any controlled-release theophylline product, the patient should alert the physician if symptoms occur repeatedly, especially near the end of the dosing interval.

DRUG INTERACTIONS Drug-Drug Toxic synergism with ephedrine has been documented and may occur with some other sympathomimetic bronchodilators. In addition, the following drug interactions have been demonstrated:

Drug

Theophylline with lithium carbonate

Theophylline with propranolol

Theophylline with cimetidine

Theophylline with troleandomycin, erythromycin

Drug-Food THEO-DUR 100 mg Sustained Action Tablets have not been adequately studied to determine whether their bioavailability is altered when given with food. Available data suggest that drug administration at the time of food ingestion may influence the absorption characteristics of theophylline controlled-release products resulting in serum values different from those found after administration in the fasting state.

A drug-food effect, if any, would likely have its greatest clinical significance when high theophylline serum levels are being maintained and/or when large single doses (greater than 13 mg/kg or 900 mg) of a controlled-release theophylline product are given.

THEO-DUR (200, 300, and 450 mg) Sustained Action Tablets: The rate and extent of absorption of theophylline from THEO-DUR 200 mg, 300 mg, and 450 mg tablets when administered fasting or immediately after a moderately high fat content breakfast is similar.

Drug-Laboratory Test Interactions When plasma levels of theophylline are measured by spectrophotometric methods, coffee, tea, cola beverages, chocolate, and acetaminophen contribute falsely high values.

Carcinogenesis, Mutagenesis, and Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic potential, mutagenic potential, or the effect on fertility of xanthine compounds.

Pregnancy Category C—Animal reproduction studies have not been conducted with theophylline. It is not known whether theophylline can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Xanthines should be given to a pregnant woman only if clearly needed.

Nursing Mothers It has been reported that theophylline distributes readily into breast milk and may cause adverse effects in the infant. Caution must be used if prescribing xanthine to a mother who is nursing, taking into account the risk-benefit of this therapy.

Pediatric Use Safety and effectiveness of THEO-DUR administered

1 Every 24 hours in children under 12 years of age, have not been established

2 Every 12 hours in children under 6 years of age, have not been established

ADVERSE REACTIONS The most consistent adverse reactions are usually due to overdose and are:

1 Gastrointestinal: nausea, vomiting, epigastric pain, hematemesis, diarrhea

2 Central nervous system: headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions

3 Cardiovascular: palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, ventricular arrhythmias

4 Respiratory: tachypnea

5 Renal: albuminuria, increased excretion of renal tubular and red blood cells, potentiation of diuresis

6 Other: rash, hyperglycemia and inappropriate ADH syndrome

OVERDOSAGE Management If potential oral overdose is established and seizure has not occurred

A Induce vomiting

B Administer a cathartic (this is particularly important if sustained-release preparations have been taken)

C Administer activated charcoal

If patient is having a seizure

A Establish an airway

B Administer oxygen

C Treat the seizure with intravenous diazepam, 0.1 to 0.3 mg/kg up to 10 mg

D Monitor vital signs, maintain blood pressure and provide adequate hydration

Post Seizure Coma

A Maintain airway and oxygenation

B If a result of oral medication, follow above recommendations to prevent absorption of the drug, but intubation and lavage will have to be performed instead of inducing emesis, and the cathartic and charcoal will need to be introduced via a large bore gastric lavage tube.

C Continue to provide full supportive care and adequate hydration while waiting for drug to be metabolized. In general, the drug is metabolized sufficiently rapid so as not to warrant consideration of dialysis; however, if serum levels exceed 50 mcg/ml charcoal hemoperfusion may be indicated

CAUTION Federal law prohibits dispensing without prescription. For full prescribing information, see package insert
Revised 6/87

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Continuing Education

Counseling Consumers on OTC Antiemetic Remedies

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Cincinnati, Ohio

and

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Professor of Pharmacology and Toxicology
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Ada, Ohio

Goals

The goals of this lesson are to:

1. explain causes and mechanisms of nausea and vomiting; and
2. discuss FDA's final rule on OTC antiemetic drug ingredients.

Objectives

At the conclusion of this lesson successful participants will be able to:

1. list common causes of nausea and vomiting, and describe the vomiting process;
2. identify antiemetic drugs and the claims that are approved by FDA for inclusion in OTC products;
3. exhibit knowledge about the pharmacology of phosphorated carbohydrate solutions;
4. choose from a list, specific warnings against the use of antiemetic drugs; and
5. provide important consumer information when counseling on nausea and vomiting and the use of OTC antiemetic drug products.

FDA announced its final rule on antiemetic products for over-the-counter use in April, 1987. This rule, to become effective in May, 1988, culminated more than 15 years of intensive review of available information pertaining to these agents. As with other FDA reviews of OTC drug ingredients, the rule defined the antiemetic ingredients that the agency recognized as safe and effective for self-administration. It also posted the claims that manufacturers can cite about their products.

Nausea and Vomiting

Nausea is a subjective feeling that vomiting may soon occur. The feeling can also occur independently of vomiting.

Vomiting (emesis) is the forceful expulsion of the gastric contents out of the mouth. Nausea and vomiting frequently occur together. Besides the obvious discomfort, nausea is also generally accompanied by pallor, increased salivation, headache, lassitude, increased perspiration, bradycardia and hypotension.

A number of conditions induce nausea and vomiting. These include events that significantly increase the pressure and tension on the wall of the esophagus, stomach, or duodenum; unpleasant odors, tastes, or thoughts; drug or radiation therapy; effects on the systemic and central nervous systems; disturbances to the labyrinths (the equilibrium centers) in the inner ears (motion sickness); and pregnancy. Table 1 lists many of the major causes of nausea and vomiting.

Nearly everyone has been nauseous on occasion and has vomited. Usually these bouts are temporary and cause no serious harm. When vomiting persists, it may signal a serious medical condition such as a brain tumor or bowel obstruction. Because nausea and vomiting may be symptoms of morbid pathology, they should receive prompt medical attention if not explained by the usual causes, i.e., by drug administration, motion or food ingestion, or if they persist.

Mechanism of Vomiting. Three anatomical centers are involved in vomiting. These are the labyrinthine (vestibular) apparatus in the inner ears, the chemoreceptor trigger zone (CTZ) in the brain stem, and the vomiting center which is located in the medulla. The vomiting center initiates and controls the actual act of vomiting. Figure 1 illustrates various steps in the complex act of vomiting.

Nausea and vomiting can follow administration of any of a number of drugs. The approved labeling of most drugs list nausea and/or vomiting as a side effect of therapy. Representative drugs which are associated with relatively high occurrence are listed in Table 2. Their mechanisms include irritation of gastrointestinal smooth muscle or stimulation of the CTZ. This form of

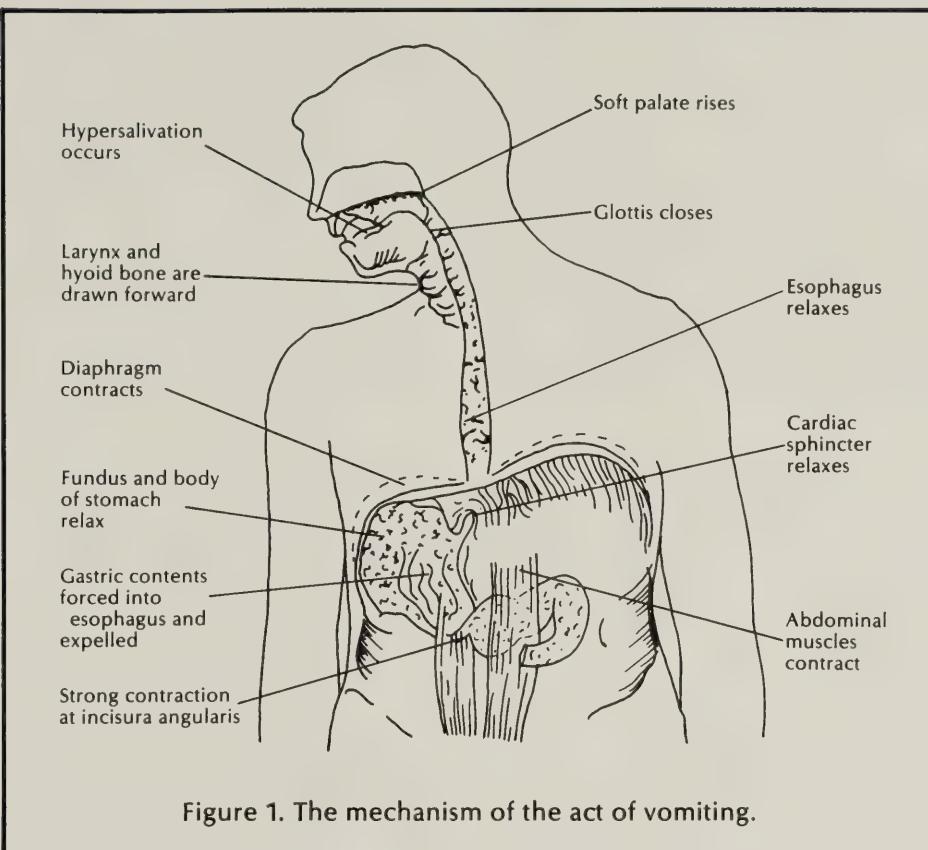


Table 1

Causes of Nausea and Vomiting

| | |
|--------------------------|------------------------------|
| Adrenal insufficiency | Labyrinthitis |
| Alcoholic gastritis | Meniere's disease |
| Appendicitis | Meningitis |
| Brain stem lesions | Migraine |
| Cancer | Motion sickness |
| Chronic indigestion | Myocardial infarction |
| Congestive heart failure | Peptic ulcer |
| Diabetic acidosis | Peritonitis |
| Drugs (see Table 2) | Pregnancy |
| Emotional upset | Psychological suggestion |
| Epilepsy | Pyelonephritis |
| Fever | Radiation therapy |
| Gallbladder disease | Raised intracranial pressure |
| Gastric irritation | Refractive errors |
| Glaucoma | Severe pain |
| Hypertensive crisis | Surgery |
| Hyperthyroidism | Unpleasant odors |
| Hypoadrenalinism | Uremia |
| Hypo/hyperparathyroidism | Vertigo |
| Infection | |

Only motion sickness is considered to be self-treatable with OTC antiemetics.

nausea is not considered to be self-treatable and OTC antiemetics are not indicated for this use. Drug-induced gastric distress is often minimized or eliminated by taking the medication with a snack or meal, or antacids. If this fails to relieve the condition, a change in dosage or therapy may be necessary.

Motion Sickness

About 90 percent of Americans are affected with motion sickness at some time. Motion sickness is the only approved indication for OTC antiemetics.

Motion sickness occurs because of malfunctioning of the labyrinthine apparatus. This structure orients a person in space (e.g., standing straight, tilted to one side, lying prone, etc.) whether his eyes are open or shut. The labyrinthine apparatus is also called the equilibrium center.

euphoria and psychosis are also recorded. Because of these actions, scopolamine is restricted to prescription use only.

The transdermal patch product containing scopolamine (Transderm-Scop) is effective in ameliorating symptoms of motion sickness. The patch steadily releases small amounts of scopolamine over a 3-day period. The drug is absorbed sufficiently to combat motion sickness, but blood concentrations are low enough to minimize side effects. The therapeutic advantage of the transdermal patch system is that scopolamine is released at a constant rate, eliminating peaks and troughs associated with conventional oral dosage forms. Transderm-Scop patches currently require a prescription for sale. However, because of its few adverse effects, its distributor is reportedly pursuing OTC marketability.

The phenothiazine derivatives (e.g., Compazine and

Table 2

Representative Drugs That Cause Nausea

| |
|---------------------------------------|
| Adrenocortical steroids |
| Cancer chemotherapeutic agents |
| Chloral hydrate |
| Digitalis glycosides |
| Estrogens |
| Iron salts |
| Nitrofurantoin |
| Nonsteroidal anti-inflammatory agents |
| Potassium salts |
| Reserpine |
| Salicylates |
| Spiromonolactone |
| Thiazides |

Table 3

Dosages for OTC Antiemetic Drugs

| NAME (generic/trade) | AGE | DOSE | DAILY LIMIT |
|--------------------------|------------|---------------------|-------------|
| cyclizine/Marezine | Adult | 50 mg q 4-6 hr | 200 mg |
| | Child 6-12 | 25 mg q 6-8 hr | 75 mg |
| | Child 2-6 | Not recommended | — |
| dimenhydrinate/Dramamine | Adult | 50-100 mg q 4-6 hr | 400 mg |
| | Child 6-12 | 25-50 mg q 6-8 hr | 150 mg |
| | Child 2-6 | 12.5-25 mg q 6-8 hr | 75 mg |
| diphenhydramine/Benadryl | Adult | 25-50 mg q 4-6 hr | 300 mg |
| | Child 6-12 | 12.5-25 mg q 4-6 hr | 150 mg |
| | Child 2-6 | Not recommended | — |
| meclizine/Bonine | Adult | 25-50 mg once daily | 25-50 mg |
| | Child 6-12 | Not recommended | — |
| | Child 2-6 | Not recommended | — |

When impulses originating from the labyrinthine apparatus are not synchronous with what a person believes to be his relative position in space, motion sickness can occur. It is prevalent when the head is rotated in two different directions simultaneously, as occurs from combined actions of a ship rolling from side to side, and pitching from front to back.

Antiemetics

Anticholinergics and antihistamines effectively alleviate motion sickness. Their mechanism of action is thought to be through reducing the excitability of receptors in the labyrinths, depressing impulse conduction through the vestibular apparatus, and/or inhibiting reception of these impulses by the CTZ.

Scopolamine is generally heralded as the most effective preventative agent in motion sickness, in the recommended oral dose of 0.6 to 1.0 mg. Oral use is limited, however, because of scopolamine's many adverse effects which include blurred vision and photophobia, constipation, dry mouth, urinary retention and reduced sweating, palpitations and tachycardia. Toxic

Phenergan), and metoclopramide (Reglan) are also effective antiemetics. Their mechanism of action is probably due to inhibiting dopamine receptors in the CTZ, thereby lessening vomiting impulses. Due to their potential adverse effects profile, these agents are not currently available OTC.

OTC Antiemetics

Four antihistamines were judged by FDA as safe and effective antiemetics for OTC use. The antinauseant activity of antihistamines appears to be due to their anticholinergic effects, in that impulses passing through the labyrinthine apparatus to the CTZ are reduced. OTC antihistamines that have been approved for treatment and prevention of motion sickness are cyclizine (e.g., Marezine), dimenhydrinate (e.g., Dramamine), diphenhydramine (e.g., Benadryl), and meclizine (e.g., Bonine).

Besides reducing the number and frequency of impulses into the CTZ, antihistamines also cause mild CNS depression leading to drowsiness. This is potentiated by alcohol and other sedating drugs.

Use in Pregnancy. Since controversy attends the use of antiemetics in pregnancy, it is interesting that the FDA/OTC advisory panel that originally studied them determined that the current restrictions are too stringent. Since the early 1960s, the warning: "Not for use by women who are pregnant or may possibly become pregnant unless directed by a physician since this drug may have the potentiality of injuring the unborn child," has been required for labeling of antiemetics. Retrospectively, the advisory panel felt that this warning was not supported by clinical evidence.

For example, its report cited data on over 50,000 pregnant women of whom approximately 1,000 took meclizine during the first trimester of pregnancy. This is the period of organ development when fetal cells are differentiating. Most birth defects occur during this time.

The FDA review showed that there was no statistically greater incidence of fetal malformation (teratogenesis) in treated women than in women who had not received meclizine. In its 1987 release, FDA stated that there is no evidence that these products cause birth defects.

Meclizine. A confusing situation has occurred in which the OTC product Bonine and the prescription product Antivert contain the same ingredient and are marketed by the same manufacturer. It can be explained.

Originally, Antivert was a combination of meclizine and niacin indicated for vertigo and Meniere's syndrome. The latter condition results in a distressful feeling of dizziness and lightheadedness that comes and goes.

During FDA's Drug Efficacy Study Implementation (DESI) review a few years ago, combination products such as Antivert were ruled to be ineffective. The manufacturer therefore removed niacin. Meclizine is effective for both vertigo and Meniere's syndrome, but these indications are not considered self-diagnosable or self-treatable. Since Antivert has remained in the "Top 200"-prescribed drugs, its manufacturer has decided to provide meclizine under two different trade name products, one indicated for OTC use, and the other for prescription distribution. The basic difference between the two products is that Bonine cannot be promoted directly to the lay public for treating vertigo or Meniere's syndrome. A similar situation exists for Benadryl 25 mg and Benadryl 50 mg strength capsules.

Diphenhydramine. The FDA advisory panels for four different groups of OTCs (antiemetics, antihistamines, antitussives and sleep aids) found diphenhydramine to be safe and effective for each indication. With the exception of sleep aids, FDA disagreed with the panels' recommendations of studying the drug further for possible OTC use. The agency was concerned with the level of drowsiness that diphenhydramine caused. Based on FDA's findings regarding diphenhydramine's OTC availability as an antitussive, how-

ever, the risk of drowsiness alone, as a side effect, did not provide sufficient reason to withhold the drug from OTC use. Diphenhydramine is now approved for OTC use for all four of the above indications, but it must be labeled with the warning: "May cause *marked* drowsiness." As of May, 1987, no manufacturer was marketing diphenhydramine as an OTC antiemetic.

OTC Antiemetic Labeling Regulations

One of the important facets of the OTC drug review process concerned product labeling. Labeling includes allowable indications (claims), warnings to the consumer about other drugs or conditions to be avoided, disease states that might be aggravated by action of the OTC ingredients, prescription drugs with which they may significantly interact, and directions for proper use.

The indication that will be permitted on OTC antiemetics is: "For the prevention and treatment of nausea, vomiting, or dizziness associated with motion sickness." No other claims can be made. The warning that must appear on all antihistamine-containing preparations including antiemetics is: "Drowsiness sometimes results from taking this product. Do not operate motor vehicles or other machinery or equipment while taking this product." This warning advises of possible additive CNS depression that alcohol and other depressant drugs can exert in addition to that caused by the antihistamine.

Manufacturers of cyclizine and diphenhydramine must also warn that they not be given to children less than 6 years of age except under physician supervision. Dimenhydrinate must contain the same warning except that the lower age limit is 2 years of age. Meclizine is not indicated for persons less than 12 years. Table 3 summarizes dosage information for OTC antiemetics.

For drug/disease warnings, the labels of antihistamine-containing antiemetics must advise consumers to obtain medical advice and supervision before self-medicating if they have asthma, emphysema, chronic obstructive pulmonary disease, shortness of breath or difficulty in breathing; glaucoma; or difficulty in urination due to prostate enlargement. Reasons for this warning are based on the drugs' anticholinergic activity. Decreased bronchial secretions can lead to increased respiratory secretion viscosity that in some asthmatics and persons with other breathing disorders, makes expectoration even more difficult. It is possible that the airway of these individuals could become obstructed to the point that breathing is seriously hindered and their condition aggravated.

Asthma does not contraindicate OTC antihistamine use. However, for their own safety, asthmatic patients should consult their physician to determine whether antihistamine usage is appropriate for them.

The majority of glaucoma patients have the less severe, chronic (open-angle) form. However, in acute (angle-closure) glaucoma, anticholinergics (e.g., anti-

histamines) may interfere with proper functioning of the Canal of Schlemm, the drainage pathway for aqueous humor. Fluid accumulates to increase the intraocular pressure, and enhance chances for eventual blindness. While there is little possibility for serious problems with antihistamines, many patients do not know the type of glaucoma they have. Again, physician supervision is in their best interest.

Men with an enlarged prostate may experience problems with anticholinergics such as decreased bladder motility and enhanced urinary retention. These may add to adverse effects caused by the physical size of the enlarged prostate pressing on the ureters making urination even more difficult.

OTC antiemetic labeling must state: "May cause drowsiness (*marked* drowsiness for diphenhydramine and dimenhydrinate); alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Do not take this product if you are taking sedatives or tranquilizers without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery."

Phosphated Carbohydrates

Solutions of phosphated carbohydrates (e.g., Emetrol) contain levulose and dextrose with phosphoric acid to adjust the pH to 1.5. The proposed antiemetic action of this combination of ingredients is based on the theory that concentrated carbohydrate solutions delay the gastric emptying time by inhibiting gastric motility. Because of the solution's high osmotic pressure, the pyloric sphincter remains closed longer than normal.

When the FDA/OTC advisory panel on antiemetic drugs issued its initial recommendations in 1975, it commented that there was insufficient evidence to prove that solutions of phosphated carbohydrates were effective antiemetics. FDA concurred in its April, 1987 rule. However, the agency stated that additional studies were under way to prove the effectiveness of this combination, and that study results will be submitted in the near future. If definitive, the ingredients will be approved. If not, phosphated carbohydrates will not be permitted to be indicated for treatment or prevention of motion sickness.

It should be noted that the specific symptom "upset stomach" has not yet been ruled on. Products containing phosphated carbohydrates or bismuth subsalicylate (e.g., Pepto Bismol) can continue to be marketed for that indication until a final ruling is made.

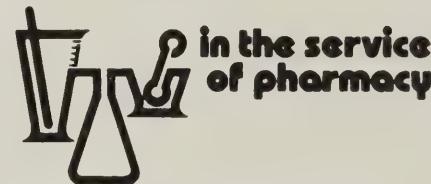
Consumer Advice

Consumers should be made aware of potential side effects of antiemetic remedies. They should be screened for the presence of any medical disorder that precludes using a particular product. They should also be directed to carefully read the instructions before taking the medication. There is presently no product in-

dicated for treating nausea and vomiting during pregnancy.

Nausea associated with motion sickness is best controlled by starting antiemetic medication one-half to one hour before the trip or event that causes the problem.

Persons affected with motion sickness can also take additional preventative measures. They should sit in the front seat in a car, and over the wing in a plane. Onboard ship, they should remain on the deck where fresh air prevails. When moving, they should focus their eyes on distant objects, or keep them closed. They should also sit in a slightly reclined position with their head braced against the seat back, and rotate their head slowly.



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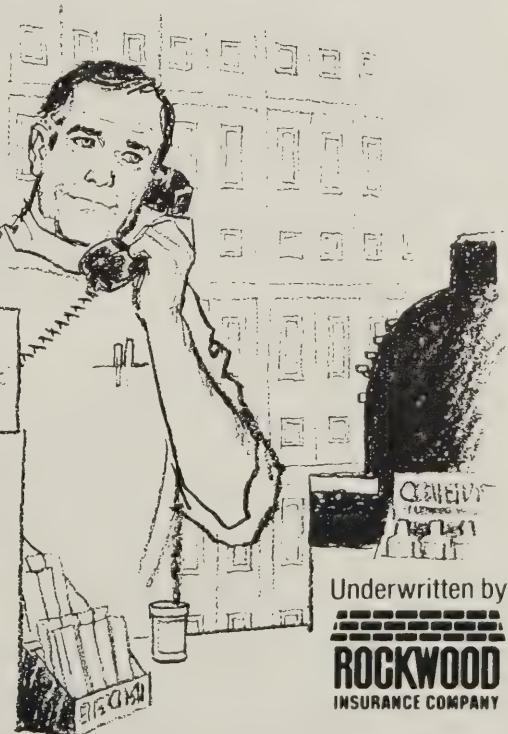
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FRAGMENTED SLEEP— A HIDDEN HEALTH HAZARD

By Martin A. Cohn, M.D.
Chief, Sleep Disorders Center
Mount Sinai Medical Center, Miami, Florida;
Assistant Professor of Medicine
University of Miami School of Medicine

Melville in *Moby Dick* admired seagulls far from land who could sit on turbulent waves and be rocked to sleep, or the sailor sleeping peacefully at sea, oblivious to herds of whales and walruses rushing beneath his pillow.

Many of us aren't so blissfully insulated during sleep. In fact, our sleep is interrupted constantly—by our own coughs, aches, worries that won't quit and a variety of physical condition. The truly bad news is that these brief awakenings—which the sleeper may not even remember in the morning—can prevent much of the good that sleep accomplishes.

Researchers now tell us that millions of people who may believe they're sleeping eight or even nine hours a night are actually getting considerably less. While we're all awakened ever so slightly perhaps 30 to 50 times each night without being aware of it, some are awakened *hundreds* of times. Scientists find this may leave them as unrested as someone who hasn't slept at all! What's more, fragmented sleep may have dramatic impact on daytime functioning and health.

What Keeps People Awake?

Many in today's world choose to get less than the usual seven to eight hours' sleep. They watch late-night TV or socialize. But others, who aim for their full allotment of sleep, are foiled.

Discontinuous sleep becomes especially common as people age, in part because pauses between breaths grow longer. As the brain senses the demand for oxygen, the individual is momentarily aroused to draw a full breath. From 50 to 150 such little "alarms" may punctuate the sleep of older persons. These can make sleep less restorative—particularly since older people have greater trouble than young people falling back to sleep.

Halts in breathing especially plague the slumber of people with a condition called *sleep apnea*. A malfunction of the sleep respiratory control center in the brain causes them to periodically stop breathing for 10 seconds to a minute or longer. They may wake up gasping for air 200 or 300 times a night.

People who snore because of an upper airway obstruction also awaken frequently to catch their breath. Since half of all people in their sixties snore regularly, this is a major cause of disrupted sleep.

Heart conditions and cerebrovascular disease—hardening of the arteries supplying blood and oxygen to the brain—can lead to fragmented sleep too. Sluggish circulation causes the brain to emit a distress call for more oxygen. The sleeper becomes somewhat alert while taking deep breaths. This "waking up" is evident on brain wave patterns but may not be recalled by the person.

Coughing while asleep, because of respiratory problems and also gastrointestinal disorders in which stomach acids rise to the throat, adds to the multitudes whose sleep is interrupted.

In addition to those who can't breathe freely are people with the sleep disorder *nocturnal myoclonus*. They automatically tense their leg muscles every 30 seconds or so during sleep. The muscle twitching leads to kicking and shifting of the legs plus many brief arousals.

Painful ailments such as arthritis and back problems often disturb sleep. Another painful condition is *fibrositis*, marked by muscle and bone pain as well as fatigue. Individuals with this muscle inflammation experience unusual nervous system activity while sleeping. Furthermore, sleep does not have its usual refreshing effect. The night-long discomfort from any painful affliction can leave a person weary even after nine hours of fitful sleep.

Anxious and depressed individuals comprise another large group who often can't sleep soundly or continuously. Those who are depressed may awaken at 3 A.M. and not recapture sleep until it is almost time to get up for work. Anxiety sufferers may toss and turn.

The Price We Pay for Fragmented Sleep

Tiredness during the day and deteriorated physical and mental performance are the chief effects of fragmented sleep. At Mount Sinai Hospital, we recently studied sleep apnea patients who go through each day in a fog, often not remembering things they have done. They fill out forms at work but don't recall doing so, or drive somewhere only to wonder how they got there. We all engage in daydreaming and some automatic behavior, but these people are almost sleepwalking. Their reflexes are slower, presenting driving dangers. Red lights may be missed. Inattentiveness can make them appear lazy or indifferent, especially if they're making frequent mistakes. An employer may fire them.

Fragmented sleep oftens leads to emotional and behavioral disturbances. Irritability and temper outbursts are common, with damaging consequences to personal and professional relationships.

In addition, medical studies support the popular belief that someone who doesn't get enough sleep will be "run down." During deep sleep, the immune system that protects the body against disease is fortified by production of new protective substances. Without sufficient sleep, people may have less resistance to disease.

People who already are ill may have greater difficulty recovering without sound sleep. Patients in a hospital's intensive care unit (ICU), who are monitored constantly and frequently awakened for tests and examinations, offer a dramatic demonstration of this. These patients are extremely sleep-deprived. They're also deprived of the full supply of hormones responsible for body tissue healing that are produced during deep sleep. Patients may develop psychological problems, informally known in the hospital as "intensive care unit psychosis." But when patients are taken from ICU and allowed three hours of uninterrupted sleep, they feel better and need smaller amounts of pain-killing narcotics or other medications.

Being well-rested, of course, reduces discomfort and increases people's ability to cope with a wide range of illnesses—from the common cold to arthritis and asthma. Extensive studies in Scandinavia show higher death rates for people who regularly sleep less than six, or more than nine, hours per night. While too little sleep may be a form of stress that aggravates heart disease and other illnesses, other factors actually may be to blame for these early deaths.

Continued on page 14.

'Tween Scripts

By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.

Honoring Pharmacy's "Extra Effort" People

Again this fall, current year recipients of the A. H. Robins "Bowl of Hygeia" Award, selected by their peers through their professional pharmacy associations in the 50 states, the District of Columbia, Puerto Rico, and the 10 Canadian provinces were invited to be guests of our company for a special salute in our Richmond headquarters.

The five-day event included receptions and dinners, tours of our manufacturing and research facilities and a sightseeing trip to Williamsburg, the restored colonial capital of Virginia.

It was a desire to encourage pharmacists to take more active roles in community affairs that prompted E. Claiborne Robins, chairman of the board of A. H. Robins Company and a pharmacist himself, to establish the "Bowl of Hygeia" Award in 1958. The award provides special recognition to the men and women of pharmacy for their many and varied community services.

Some have served in their state legislatures and on city councils. Others have filled important positions on planning and zoning commissions and hospital, school and other boards. They have provided leadership for fund drives and countless special projects, and have participated in the work of youth organizations, civic clubs, churches and fraternal organizations. Perhaps a quarter of the 1,700 plus recipients thus far have headed their state or provincial pharmaceutical associations at one time or another.

The award is a handsome plaque featuring the Bowl of Hygeia cast in bronze. So that they may be recognized wherever they go, award winners are also presented lapel pins which are scale replicas of the plaque, and at any gathering of pharmacists, those wearing the pin form a proud "alumni" of previous recipients.

A. H. Robins is pleased to be able to assist state and provincial associations in recognizing these "extra effort pharmacists."

Jake Miller
A-H-ROBINS

A. H. Robins Company
P. O. Box 26609
Richmond, Virginia 23261-6609

Fascinating studies have shown that rats deprived completely of REM (rapid eye movement) sleep will become ill and die, usually in about a month. The rats studied lost only about a quarter of total sleep time yet were profoundly affected. REM sleep in humans is when dreaming occurs along with other physical events while the eyes move under closed lids. Implications for humans are not clear; while many sufferers of fragmented sleep tend to be awakened only during REM periods, fortunately they still retain much such sleep.

Studies of people and animals subjected to extensive sleep deprivation may have relevance for those who suffer fragmented sleep—especially in light of findings that a great many sleep interruptions are comparable in effect to total deprivation. For example, epileptic rats have seizures more easily when sleep-deprived than when well-rested. Some people who have *panic disorder*—an anxiety disorder characterized by sudden attacks of irrational terror and accompanying feelings of choking, pounding heart, dizziness and sweating—had these attacks more often on the day after being deprived of a night's sleep.

Getting a Full Night's Sleep

The best recipe for sleeping well is living well—cultivating habits that invite a full night of restful sleep. These include getting to bed and awakening eight or so hours later on a regular schedule, since changing bed-

times can confuse a person's "inner clock"; exercising moderately (but not just before sleep); avoiding naps; refusing caffeine and alcohol in late evening; and refraining from upsetting activities such as violent TV programs or paying bills just before bedtime. When something does interfere with a night's sleep, a strategic nap sometimes can undo the harm and allow people to function as if they had slept well—but, as a rule, it's best not to make a habit of naps.

Light sleepers can use some commonsense measures. If sleep is fragmented by a husband's or wife's snoring, the nonsnorer should go to sleep first. A person is not as apt to be awakened from sleep as to be prevented from falling asleep. If exterior noise intrudes, sound-screening curtains, acoustic tiles or earplugs can solve the problem.

Those who suffer fragmented sleep for any of the causes discussed should seek professional help. A personal physician may be able to treat insomnia as well as anxiety and depression, prescribing effective medications as well as providing, or referring the patient for, helpful counseling. Specialized sleep disorders centers can evaluate problems such as sleep apnea, leg muscle spasms and snoring and guide the patients to effective treatments.

Primarily, one should be aware that agitated, fragmented sleep can have serious repercussions. Take the necessary steps to get a good night's sleep on a regular basis. *It's important!*

COMMON MYTHS ABOUT SLEEP AND THE ELDERLY

By J. Christian Gillin, M.D.
Professor of Psychiatry
University of California, San Diego

As a sleep disorders expert, I encounter many misconceptions about sleep that concern elderly patients in particular—perhaps because they're the group most likely to suffer from sleep disorders.

Some common misconceptions about sleep and older people include the following:

Myth #1: As we grow old, we need less sleep than we did when we were younger.

Fact: The elderly may get less sleep, but their individual needs for a specific amount are relatively constant. As the body ages, the quality of sleep deteriorates. Sleep becomes less efficient and is often light and unrestful. By age 50 for men and 60 for women, sleep is usually devoid of the two deepest stages, those considered to be the most refreshing and restorative.

While the elderly are the group most prone to sleep problems, many of these difficulties can and should be treated.

Myth #2: Napping during the day will not interfere with sleeping at night.

Fact: Insomnia is often exacerbated by taking naps during the day. Napping almost always decreases the quality and quantity of nighttime sleep. Poor sleepers who catnap during the day also find that it usually takes longer to fall asleep at night. In rare cases, however, those who suffer from very severe insomnia may be too exhausted to fall asleep at night unless they have had a nap. For these people, sleep experts recommend taking a nap regularly at the same time each day.

Myth #3: A nightcap before bed is a good sleep aid.

Fact: In the long run, alcohol makes sleep worse, not better. Although a shot of whiskey or a glass of wine may relax the weary insomniac enough to fall asleep, once the alcohol is metabolized, the body enters a state of withdrawal. The result is frequent awakenings and a drop in the overall quality of sleep.

Myth #4: Snoring may be annoying, but it is not dangerous.

Fact: Snoring is no trivial matter. It almost always indicates that something is wrong with breathing during sleep. A particular pattern of very loud snoring accompanied by pauses in breathing that last from 20 to more than 100 seconds is a sign of a potentially life-threatening condition called *sleep apnea*. Sleep apnea tends to occur most often in elderly or overweight men and has been linked to high blood pressure, heart attacks and strokes. A 1987 study found that apnea occurred during sleep in 38 percent of the male patients over the age of 60 in the Veterans Administration Medical Center at San Diego, Calif.

Anyone may have occasional brief pauses in breathing during the night. Those with sleep apnea, however, stop breathing more than five times each hour, up to a minute or longer each time, and often wake up gasping for breath. (Individuals with sleep apnea should consult their physicians about taking sleep medications or drinking alcohol in the evening, as these substances may make their breathing difficulties worse.)

Myth #5: Sleep medications available over the counter are safer than prescription drugs.

Fact: Nonprescription sleeping pills are not innocuous. Their active ingredient is antihistamine, which can produce disturbing side effects, including disorientation, dizziness, ringing in the ears, poor coordination, blurred or double vision and irritability. In addition, some antihistamines are long-acting and may produce carryover drowsiness the next day.

Myth #6: Sleeping pills are never safe for elderly people.

Fact: While there is no perfect sleep medication, the National Institute of Mental Health has recommended the benzodiazepine group as the sleep medications of choice, emphasizing that elderly patients in particular should be prescribed the smallest effective doses for the shortest period of time.

Within the benzodiazepine group, however, those that are more rapidly eliminated from the body have been shown to be generally safer for elderly people. A recent study found that long-acting benzodiazepines may make elderly patients more likely to fall and suffer hip fractures. No increase in falls was detected when patients received short-acting sleep medications.

The need for daytime alertness should be a major consideration whenever sleep medications are prescribed—particularly for the elderly to whom a fall can be a life-threatening event.

Commentary

Dickinson's Pharmacy

Jim Dickinson

Technicians—or pharmacists? If it seems to the bright young pharmacists of today that it's somehow "mundane" or even "degrading" to fill prescriptions, then maybe it is the bright young pharmacists who are "degrading"—degrading the profession of pharmacy, that is.

That aggressively stated opinion, straight from the lips of pharmacist William Day at the NARD annual convention in October, presents one important aspect of the intensifying controversy over pharmacy technicians.

Another, counterbalancing viewpoint was given by Henri R. Manasse, Dean of the University of Illinois pharmacy school and arguably the profession's most challenging thinker. Describing what he called "appropriate task delegation" in other health fields, he said the time for this is here in pharamacy, too—"we can not expand our practice responsibilities without concomitantly delegating those tasks which can be appropriately delegated to a new occupational class. That class ought to be the *pharmacy technician*."

The two viewpoints dramatize an old, and to some minds, boring professional skirmish that's economically rooted. That older version of the debate has always maintained that you could do away with most of your employee pharmacists if only you could persuade the politicos that technicians count-and-pour, lick-and-stick equally as well as pharmacists for a fraction of the price.

Think of the cost-containment! And there's no doubt that some (non pharmacist) comptrollers of corporate chains, mail-order firms and HMOs are attracted to the first blush of the concept.

But Day and Manasse were talking about a more sophisticated disagreement on that old theme.

You need to pay attention if you want to see the all-important differences between their positions—and to see the peril to pharmacy if these differences aren't addressed.

First, Day's view actually lauds the act of counting and pouring—the physical exposure of the tangible medication to the pharmacist's naked eyes, nose, and maybe fingers as well. This is too important a function and a public protection to be delegated to the unknowing, almost robotic touch of parapharmacists.

Continued on page 17.

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Second, Manasse's view is that it's not all *that* important—there are much more important things that expensive pharmacists could and should be doing. Like counseling and advising in a new age of expanding numbers and complexities of pharmaceuticals. In that context, there's already such a grossly under-recognized shortage of pharmacists that relief through technicians is needed.

Enter a third primary viewpoint, that of Texas Pharmaceutical Association past president Bob Gude at the NARD convention: "I feel that pharmacists should be held legally responsible for counseling patients to the same degree that we are now held legally responsible for identifying and preventing prescribed overdoses . . . At the present time, while we have the education of a professional, we have the legal status of a technician. That is why so many of us feel threatened by technicians."

So we have a triangle. At one corner is the professional pharmacist's attitude to handling and sensually assessing the potent, toxic dosage forms moving under his or her cognition. At another is the role of professional counselor and advisor about these powerful agents—a role that everyone recognizes is not being fully filled by all pharmacists, for a variety of reasons among which is the lack of time to counsel or advise. And at the third is the law's presently low expectations of pharmacists—a standard that recent decisions are slowly raising, but arguably not as fast as public expectations are rising.

Within the area bounded by the sides of this triangle are the technicians themselves—limited by law, by public expectations, and by pharmacist perceptions.

Journal of Pharmacy Technology editor Pat Dexter, herself a former technician, told NARD there's no need for all the antagonism some pharmacists have.

While a small fraction of the total technician workforce does have professional ambitions these do not include displacement of pharmacists in any work setting. The overwhelming majority of technicians are just passing through (functionary clerks, and clerks who specialize in pharmacy)—as such, they have minimal ambitions so far as learning what real pharmacy is all about and advancing in it.

The "career pharmacy technician," on the other hand, wants to understand pharmacy, and to support the pharmacist optimally, through training, education and certification. No survey has ever been done of this breed, to which Dexter belongs, but she's sure they're a tiny minority and that they would not want to displace a single pharmacist in any facility, such as a mail-order company.

"Mail-order technicians are just clerks," Dexter told me after the convention. "Career technicians just would not ever work in a mail-order facility—at least, I wouldn't!"

So the menacing cloud of technician-driven factories closing out pharmacist career opportunities is fantasy, say Dexter and Manasse.

Gude doesn't go that far, but he says the way to allay pharmacist's fears about it is to legally hold the profession's feet to the counseling fire, to dramatize for all the clear functional—as opposed to educational—difference between technicians and pharmacists.

What is the critical difference that the rhetoric has been obscuring all these years?

It is the *legal* function of pharmacy dispensing. And if that's *only* counting-and-pouring, licking-and-sticking, then dispensing may be "degrading" to an educated, bright new pharmacist. And of course a technician could do it—if the legal responsibilities were rewritten to allow that.

Even without such rewriting, technicians of a kind are probably doing it illegally all the time right now, in certain places.

But if dispensing is all the things that the Henri Manasses and the Bill Days and the Bob Gudes—and you—say it is, then Pat Dexter is right in her reassurances, too. The technician is there to enhance the pharmacist.

I'll give the last word to Manasse, because I think he is right on the button: "I do not believe that we could be meeting the professional service demands of the American public if we did not presently and broadly employ them in our respective pharmacy practices."

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Victoria Ann-Lewis moves so gracefully on stage the audience doesn't even know she has polio.



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Community Forum

This and That About Pharmacy

Leon Weiner, P.D.

SICK CALL . . .

Best wishes for a continued recovery to BMPA President Paul Zucker ('58). He is one of the owners of Burris and Kemp Pharmacy in Baltimore.

Best wishes for a speedy recovery to Thomas Patrick ('55). Current president of the Alumni Association Tom is associated with the University Hospital Pharmacy.

NEWS IN BRIEF . . .

Jeffrey A. Bernstein from Maryland and classmate Paula from Ohio met while attending Ohio Northern University in Ada, Ohio. Both graduated in 1982, then married and moved back to Maryland. They then worked for People's Drug Stores until opening Laurel Park Pharmacy in Laurel, MD. They have one child, Sara, who is 18 months old.

Just a few days before his 70th birthday, pharmacist Gil Dunn was attempting to break in one of his young horses. Unfortunately, the horse bolted and both Gil and his mount went down. Gil was rushed to the hospital unconscious. Remarkably, in just three days he was back at work in Kent Island Pharmacy filling prescriptions. Gil's secret? Regular jogging keeps him fit.

Congratulations to Janet Michael Abramowitz ('81) and husband Alan on the birth of their eight pound son Aryeh on July 10, 1988. They also have two other children, Sarah, age six, and Yonah, age three.

Nick Wischuck recently wrote a fine article entitled "Warm Memories of Living in Sparrows Point: 1939-1945." Born and raised in Pennsylvania, Wischuck moved to Baltimore in 1939 to work for Bethlehem Steel. While working at the Point, he met Frank Wesolowski, a welder. Frank's family ran a grocery store in Edgemere on Sparrows Point Road. Frank asked Wischuck to help out with the first organized football team program in Edgemere in 1943. He accepted the offer, inherited the team, and did very well winning the division title in 1945. Frank went on to graduate from the U of M Pharmacy School in 1956. He was been the owner of Valley Pharmacy on York Road in Lutherville for many years.

Congratulations to Dean William J. Kinnard, Jr. who has now served the Maryland pharmacy community as Dean of the University of Maryland School of Pharmacy for 20 years.

One of the happy guests at an 8/8/88 party was Ted Sophocleus ('62), owner of Ted's Linthicum Pharmacy in Baltimore County. The party was featured on Channel 13's Eyewitness News.

Linda Jean Gray ('83) recently married Dr. Lawrence A. Jones, a urologist in Hagerstown, MD. She met him while working as a representative for Hoffman-LaRoche. Linda is currently working at Boonsboro Pharmacy and was instrumental in revitalizing the Washington County Pharmaceutical Association.

Edmond J. Kucharski ('84) and Kathrine E. Choate ('87) were married in the summer of 1987. They have recently moved into a new house in the Westminster area. Ed works for Powell Pharmacy in Columbia and Kay is starting a job with Church Hospital.

According to John Steadman, sportswriter for the Baltimore Sun, there's a good chance a professional baseball team may come to Ocean City, MD. The drive to get a minor league franchise is led by Bob Welsh ('55). Welsh operated a pharmacy in Ocean City for 25 years until he sold it in 1987. "Imagine what minor league baseball would do for our area. Ocean City is a family resort and baseball is family entertainment. It would be a place to go at a reasonable price. There's no doubt it can be successful," says Welsh. We wish Bob Welsh, Mayor Roland "Fish" Powell, Paul Welsh, Charley Meagher, Hal Glick, Chip Gordy, county Commission President Bennett Bozman and all others much success on this fine project.

Mr. and Mrs. William Tabak have announced the marriage of their daughter Nancy Susan to Philip Marc Braverman. Bill ('61) is employed by the Rite Aid Drug Co.

Kimberly Ann McKenna ('88) and Raymond Anthony Palasik ('88) didn't think three years of Pharmacy School was long enough. Instead they got engaged and will wed this year. Kimberly is employed by People's Drug and Ray works for Giant.

Joseph Kempler, son of Jerry Kempler ('65) and wife Myra, is engaged to Ellen Kaplan and will be married this fall. Jerry's store is Howard and Morris Pharmacists on North Charles Street.

PHARMACY PASSINGS . . .

Condolences to Joseph V. Brazius ('57) of Howard County on the passing of his wife Brethner Lorene on September 10, 1988.

Albert M. Silverman ('28) passed away on September 30, 1988. Silverman was the owner of Highland Pharmacy in East Baltimore for 54 years. After retiring in 1986, Al enjoyed golf and working with the stock market. He was a member of AZO Fraternity.

Edward B. Markley ('30-Pittsburgh) died on September 26, 1988. He was the owner of Markley Pharmacy on Falls Road in Baltimore between 1946 and 1966. After selling the store, he worked for Read's Drugs and later in real estate. Ed, a member of AZO Fraternity, greatly enjoyed art and gardening.

Condolences to Larry H. Pozanek ('59) on the death of his mother Jean on September 7, 1988. She was also the grandmother of Keith Pozanek ('86).

Pharmacy Changes—September 1988

NEW PHARMACIES:

| | |
|--|--|
| F & M Pharmacy #51 602 Quince Orchard Rd. Gaithersburg, MD 20878 | Safeway Pharmacy #837 5800 Silver Hill Road District Heights, MD 20747 |
| Weis Pharmacy #130 221 Muddy Branch Road Gaithersburg, MD 20878 | The Medicine Shoppe 8541-K Fort Smallwood Rd. Riviera Beach, MD 21122 |
| Rodman's Discount Food and Drug 14703-A Baltimore Blvd. Laurel, MD 20707 | |

Delaware
Maryland
West Virginia
Virginia
South Carolina
Washington D.C.

LILLY DIGEST AVERAGES OF SELECTED OPERATING STATISTICS

| AVERAGES PER PHARMACY | 1987 SOUTH ATLANTIC REGION (216 Pharmacies) | 1986 SOUTH ATLANTIC REGION (162 Pharmacies) | 1987 AVERAGE UNITED STATES (1,806 Pharmacies) |
|---|--|--|--|
| SALES | | | |
| Prescription..... | \$451,899— 73.7% | \$401,243— 69.3% | \$450,815— 66.5% |
| Other..... | 161,113— 26.3% | 177,442— 30.7% | 227,333— 33.5% |
| Total Sales..... | \$613,012— 100.0% | \$578,685— 100.0% | \$678,148— 100.0% |
| COST OF GOODS SOLD | | | |
| GROSS MARGIN..... | 417,741— 68.1% | 389,129— 67.2% | 460,660— 67.9% |
| EXPENSES | | | |
| Proprietor's or Manager's salary | \$ 41,209— 6.7% | \$ 39,310— 6.8% | \$ 42,650— 6.3% |
| Employees' Wages | 54,670— 8.9% | 55,652— 9.6% | 63,588— 9.4% |
| Rent..... | 13,034— 2.1% | 12,142— 2.1% | 15,931— 2.4% |
| Miscellaneous Operating Expenses | 62,267— 10.2% | 62,788— 10.9% | 72,607— 10.7% |
| Total Expenses..... | \$171,180— 27.9% | \$169,892— 29.4% | \$194,776— 28.8% |
| NET PROFIT (before taxes) | | | |
| Add proprietor's withdrawal..... | \$ 24,901— 4.0% | \$ 19,664— 3.4% | \$ 22,712— 3.3% |
| | 41,209— 6.7% | 39,310— 6.8% | 42,650— 6.3% |
| TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit) | | | |
| | \$ 65,300— 10.7% | \$ 58,974— 10.2% | \$ 65,362— 9.6% |
| VALUE OF INVENTORY AT COST AND AS A PERCENT OF SALES | | | |
| Prescription..... | \$ 48,133— 10.7% | \$ 42,290— 10.5% | \$ 47,096— 10.4% |
| Other..... | 33,659— 20.9% | 39,637— 22.3% | 48,790— 21.5% |
| Total Inventory..... | \$ 81,792— 13.3% | \$ 81,927— 14.2% | \$ 95,886— 14.1% |
| ANNUAL RATE OF TURNOVER OF INVENTORY | | | |
| FLOOR AREA* | 5.2 times | 4.9 times | 4.9 times |
| SALES PER SQUARE FOOT* | 2,656 sq.ft. | 2,552 sq.ft. | 2,824 sq.ft. |
| RENT PER SQUARE FOOT* | \$233.13 | \$227.56 | \$233.02 |
| NUMBER OF PRESCRIPTIONS DISPENSED | \$ 4.90 | \$ 4.76 | \$ 5.64 |
| New..... | 17,695— 60.4% | 15,248— 53.4% | 18,322— 62.5% |
| Renewed..... | 11,589— 39.6% | 13,314— 46.6% | 11,011— 37.5% |
| Total Prescriptions..... | 29,284— 100.0% | 28,562— 100.0% | 29,333— 100.0% |
| PRESCRIPTION CHARGE | | | |
| | \$15.43 | \$14.05 | \$15.37 |
| NUMBER OF HOURS PER WEEK | | | |
| Pharmacy was open..... | 58 hours | 60 hours | 60 hours |
| Worked by proprietor | 56 hours | 47 hours | 54 hours |
| Worked by employed pharmacist(s) | 27 hours | 35 hours | 31 hours |

* Based on averages of pharmacies that reported all data.

** Source: 1988 *Lilly Digest*

PHARMACY CLOSINGS:

Mercer's Pharmacy
301 W. Market Street
Frederick, MD 21701

Family Pharmacy
20528 Germantown Road
Germantown, MD 20874

NAME CHANGES:

Rite Aid #309
140 Village Shopping Ctr.
Westminster, MD 21157
(formerly Sentry Drug)

Uplift Pharmacy
601 60th Place, Suite A-1
Fairmount Heights, MD 20743
(formerly Paramount Pharmacy)

LOCATION CHANGES:

McDougall's Pharmacy
887-D Sandosky Road
Sykesville, MD 21784

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Particular Sales Subject To Maryland Retail Sales Tax

Sales of tangible personal property in Maryland are presumed subject to sales tax unless specifically exempted or excluded from the tax by statute. The following paragraphs describe several exemptions in the statute, accompanied by lists of items which do *not* fall within the requirements for claiming the exemption. Sales of these items are, thus, subject to sales tax unless exempt or excluded under another provision of the statute, for example, as a sale for resale or a sale made to an organization exhibiting a sales tax exemption certificate.

Food

The Retail Sales Tax Act provides several exemptions for sales of food for human consumption, including sales of food for less than \$1.00. The Act also provides a specific definition of "food". The following list contains illustrative examples of items which are not "food" under this definition, the sales of which, therefore, do not qualify for any of the exemptions for sales of food.

| | |
|----------------------|------------------------------------|
| Alcoholic Beverages | Fudge Mix |
| Bottled Water | Ice |
| Candy | Marshmallows |
| Candy-Coated Peanuts | Peanut Brittle |
| Caramel Popcorn | Pet Food |
| Chewing Gum | Roll Candy |
| Confections | Soft Drinks in Unopened Containers |
| Dietetic Candy | |

Agricultural Supplies

The Retail Sales Tax Act provides an exemption for the sales of certain enumerated items for agricultural purposes. The following list contains illustrative examples of items which are not included in this exemption, the sales of which are, therefore, subject to tax.

| | |
|----------------------------|--------------|
| Bird Seed | Grass Seed |
| Christmas Trees | House Plants |
| Fertilizer for Lawns | Shrubbery |
| Flowers | Wreathes |
| Garden Tools and Equipment | |

A vendor may not charge sales tax on any sale of trees, shrubbery or sod where he is obligated to plant or install these items. A vendor purchasing trees, shrubbery or sod for the purpose of resale on an installed basis shall pay the tax based on the purchase price of the item.

Clip and post this chart near your cash register(s).

Medicine and Medical Supplies

The Retail Sales Tax Act provides an exemption from the tax for sales of medicines, medical supplies and sickroom equipment. The following list contains illustrative examples of items which are not medicine, medical supplies or sickroom equipment, as those terms are defined by regulation, the sales of which are, therefore, subject to tax.

| | |
|--------------------------|-------------------------------|
| Athletic Supports | Prophylactics |
| Breath Fresheners | Sanitary Napkin Belts |
| Contact Lens | |
| Cleaning Solutions | Skin Creams and Lotions |
| Cosmetics | Sleep Suppressants |
| Denture Adhesives | Sunglasses (non-prescription) |
| Deodorants | Suntan Lotions |
| Disinfectants | Talcum Powder |
| Hair Care Products | Toothbrushes |
| Heating Pads | Toothpastes |
| Hot Water Bottles | Vaseline (plain) |
| Pregnancy Detection Kits | |

Miscellaneous Items

Sales of the following items are also taxable unless purchased for resale or otherwise exempt by statute, for example, as a sale to an exempt entity.

| | |
|---------------------|----------------------------|
| Air Fresheners | Kitchen Utensils |
| Anti-Freeze | Lighter Fluid |
| Appliance Rentals | Linens |
| Baby Bottles | Lubricating Oils |
| Brooms | Luggage |
| Brushes | Magazines |
| Bug Sprays | Mops |
| Cameras | Motor Oil |
| Candles | Musical Instruments |
| Charcoal Briquettes | Paper Products |
| Cleaning Products | Photographic Supplies |
| Clothing | Polishes |
| Dishes | Pots and Pans |
| Disposable Diapers | School Supplies |
| Dyes | Shaving Products |
| Eating Utensils | Smoking Deterrents |
| Film | Sponges |
| Film Developing | Sporting Goods |
| Furniture | Stationery |
| Glassware | Tobacco, except cigarettes |
| Glue | Toys |
| Greeting Cards | Water Softeners |
| Hardware | |
| Jewelry | Waxes |

Additional information concerning this Bulletin or the taxability of items not contained in these lists may be obtained from Taxpayer Service Section by telephone at (301) 225-1300.



Get ready for the Second Annual MPhA Legislative Breakfast on January 25, 1988. Watch your mail for registration information and more details.



Governor Schaefer, shown here with Maddy Feinberg and Nat Futerl at last year's breakfast, is expected to attend again this year.



Thomas Gossel, Ph.D., from Ohio Northern University will be speaking on New Drugs for 1988-1989 at the MPhA Mid Year. Merrell Dow Lakeside has provided an educational grant-in-aid to bring this program to you.



Richard Wuest, Pharm.D., from the University of Cincinnati School of Pharmacy will be a presenter at the February 5, 1989 Mid Year Meeting at the Annapolis Ramada Inn. For registration information, contact the MPhA office at (301) 727-0746.

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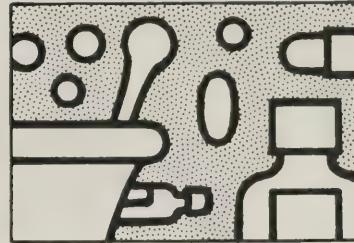
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Show your patients pharmacy is a service

Do your patients think of pharmacy as a service or as a commodity? If they see pharmacy as a commodity, how can you help them see it as a service?

1. Tell people how your services are different. All the innovative practice in the world won't get you more clients if you don't promote your uniqueness.
2. Follow through on whatever you start. If you discontinue a service or practice, tell people why.
3. Invite patients to seminars on medications or diseases periodically.
4. Establish a patient advisory board and meet with it once a month.
5. Survey the patients in your area to find out what services they're most interested in. Then provide those services.
6. Solicit comments. Send patients a follow-up postcard asking, "How did you like our services?"
7. Act on all feedback—positive and negative—even if you just explain why you can't do something.
8. Increase pharmacist and patient contact by assigning assistants to tedious tasks.
9. Send or give out product information with two tea bags; invite patients to have a cup of tea at home while they read the information.
10. Send a pharmacist to the home to consult with patients on medications.
11. Visit retirement and nursing homes and service organizations; invite residents to bring all their medications to you for counseling.
12. Make your prescription area accessible—put it up front.

Things You Should Know FOR YOUR GOOD HEALTH



Recipe for Sound Sleep: Alcohol is Not an Ingredient

Insomnia can drive some people to drink, but downing a few hot toddies before bedtime can make a good night's sleep even more elusive. Consuming two — or three or four — shots of alcohol may "knock out" the weary insomniac, but that nightcap may damage the quality of sleep for the rest of the night. And in some cases, alcohol can trigger life-threatening health problems.

Alas, the before bedtime cocktail is too often among the misguided but well-intentioned home remedies for insomnia. Experts differ on exactly the amount of alcohol that will affect sleep, but some believe that even a shot of liquor taken an hour or less before going to bed disturbs the pattern of slumber, making it light, unsettled and less than refreshing.

The person initially lulled to sleep by drink may sleep soundly for the first few hours, but then awaken or sleep poorly. The sleeper may also experience nightmares and feel unusually tired the next day. People who drink regularly may experience nightmares on nights that they refrain from alcohol.

The potential for abuse of this insomnia "home cure" is high because the amount of alcohol needed to invite drowsiness increases rapidly in a short time with regular use.

What is Insomnia?

As many as 33 percent of adults in the United States report that they suffer from occasional sleep problems, and an estimated 10 million adults annually seek doctor's advice about the problems. Insomnia is defined as the complaint of unsatisfactory sleep, and it can appear as difficulty in falling asleep, difficulty in staying asleep or lack of refreshing sleep. Insomnia is not a disease, but the sign of an underlying problem — often one that deserves medical attention.

Most normal sleepers have probably experienced *transient insomnia* — a disruption in sleep for one to three nights. Jet travel across time zones or hospitalization for elective surgery may induce transient insomnia.

Short-term insomnia, lasting from three nights to three weeks, may be caused by personal problems such as the death of a loved one or by loss of a job. Although this type of insomnia usually disappears a few weeks after the specific stress lessens, sleep medications are often helpful in the interim. Your pharma-

cist can advise you of over-the-counter remedies that may be useful for the short-term.

Long-term insomnia, lasting more than three weeks, may stem from chronic medical illness, depression or other psychiatric problems, alterations in biological clocks, chronic drug or alcohol misuse, anxiety about sleep, poor sleeping habits, or a sleep disorder such as nocturnal *myoclonus* (thrashing of the legs during sleep) or sleep *apnea* (a breathing problem).

Insomniacs in search of sleep are sometimes tangled in a Catch-22. The more worried the weary person is about falling asleep, the more tossing and turning is likely to follow.

The caution against using alcohol as a self-help for insomnia does not rule out commonsense steps that may alleviate the problem. Of course, if sleeplessness persists, a trip to the doctor is in order to determine the root of the problem and find a treatment.

For an occasional problem:

- Instead of taking an alcoholic drink, try a glass of warm milk or a light snack.
- Exercise during the day or in the early evening but avoid strenuous activity too close to bedtime, as this may be more stimulating than relaxing.
- Avoid caffeine and nicotine before retiring — both are stimulants.
- Read, listen to music, watch television or do anything else that invites drowsiness. Avoid going to bed before feeling sleepy.
- Try to get up at the same time every day to establish a solid sleep and wake cycle.

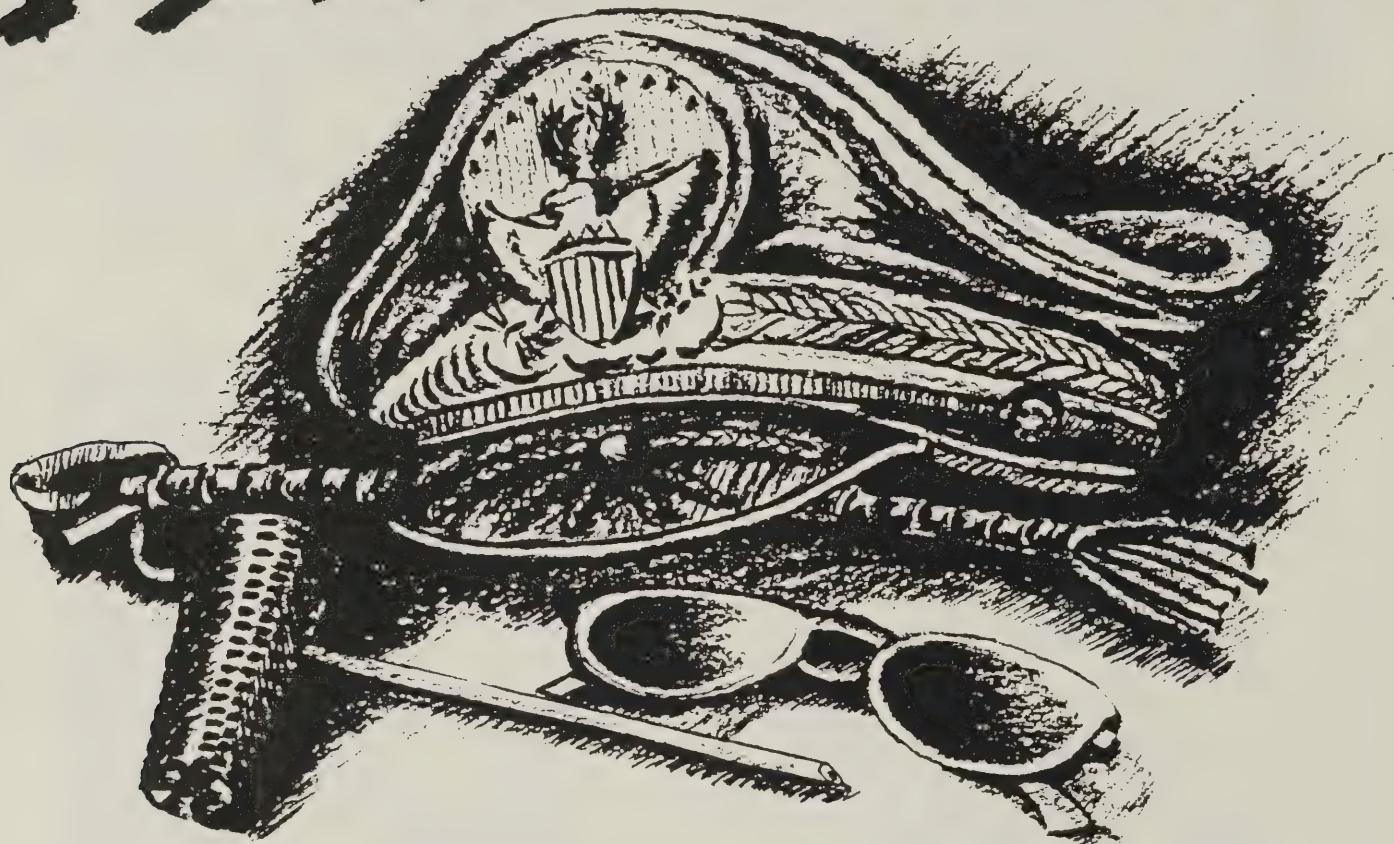
And, if all else fails, sometimes the oldest home remedy — counting sheep or any other object — may prove distracting enough to lull to sleep all but the anxious sheep rancher.

For those who want more information about insomnia, the booklet "What You Should Know About Insomnia" can be obtained by writing to INSOMNIA/UPJOHN, Dept. BY, Box 307, Coventry, CT 06238.

For the location of nearby sleep disorder centers, write: Association of Sleep Disorder Centers, P.O. Box 2604, Del Mar, CA 92014.

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National Forum

USP DI to Include FDA's "Orange Book"

Approved Drug Products and Legal Requirements is the title of a new Volume III to be added to *USP DI* for the 1989 (Ninth) edition. This third volume will contain federal and state requirements relevant to the dispensing situation, including:

- the entire text of FDA's "Orange Book," *Approved Drug Products with Therapeutic Equivalence Evaluations*;
- abstracted USP-NF monograph requirements relating to strength, quality, purity, packaging, labeling, and storage;
- selected USP-NF General Chapters and General Notices particularly applicable to the practice situation;
- selected portions of the federal Controlled Substance Act Regulations;
- the federal Poison Prevention Packaging Act and Regulations;
- the federal Food, Drug and Cosmetic Act requirements as they relate to human drugs, including the recent drug diversion and sampling amendments;
- FDA's Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals.

Plans also call for selected portions of each state's pharmacy practice act and regulations for dispensing, including product selection regulations, to be distributed in a special *Update* to the subscribers in that state.

USP DI Volume III will be updated bimonthly along with Volume I, *Drug Information for the Health Care Professional*, and Volume II, *Advice for the Patient*, as part of the regular *USP DI Update* service.

The *FDA Approved Drug Products with Therapeutic Equivalence Evaluations* is currently sold by the Government Printing Office at \$79 for a one-year subscription. The American Pharmaceutical Association had testified at FDA's bioequivalence hearings in 1986 that FDA should find a way to make the "Orange Book" less expensive and more usable. FDA's Bioequivalence Task Force subsequently recommended: "Efforts to decrease the cost should be explored [such as] by enlisting the assistance of a private organization to make the book available at a lower cost."

If purchased with any other *USP DI* subscription, Volume III, *Approved Drug Products and Legal Requirements*, will cost \$49. If purchased alone, *USP DI* Volume III will cost \$59.

Specialty Areas Recognized

The Board of Pharmaceutical Specialties (BPS) has recognized two areas of pharmacy practice as pharmacy practice specialties: nutrition support pharmacy and pharmacotherapy.

At its meeting held in Chicago on Friday, October 14, 1988, BPS voted to approve the petitions requesting specialty recognition from the American Society for Parenteral and Enteral Nutrition (ASPEN) and the American Society of Hospital Pharmacists (ASHP)—the joint sponsors of the nutrition support pharmacy petition, and from the American College of Clinical Pharmacy, the sponsor of the pharmacotherapy petition.

In each instance, the final decision for approval was based on additional information supplied by the petitioners at the request of the Board. After the review of the two petitions at its July 1–2, 1988 meeting, BPS indicated that it was asking each petitioner to clarify several points in their petitions.

In his letter notifying the sponsoring organizations of their respective specialty recognition, BPS Chairman John M. Owen, Jr. indicated the Board of Pharmaceutical Specialties' pleasure in having the opportunity to work with the petitioners. "Because of your dedication to the advancement of pharmacy as a profession and the cooperative spirit that characterized your continuous dialogue with the Board, pharmacists and the public will be better served through the certification of pharmacists in your specialty area."

BPS will work now with the sponsoring groups to establish specialty councils. Each specialty council will be charged to recommend standards and other requirements for certification of pharmacists in the specialty; to develop and administer examinations as required; and to evaluate the qualifications of individual pharmacists for certification.

The only other specialty in pharmacy, nuclear pharmacy, was recognized by BPS in 1978.



THE LOWER RESPIRATORY TRACT— More vulnerable to infection in smokers and older adults



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For respiratory tract infections due to susceptible strains of indicated organisms.

Summary.

Consult the package literature for prescribing information.

Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β-hemolytic streptococci).

Contraindication: Known allergy to cephalosporins.

Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in

moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.

● Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

● Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include

● Gastrointestinal (mostly diarrheal): 2.5%

● Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.

● Hypersensitivity reactions (including morbilliform eruptions, pruritis, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthritis, and frequently, fever]: 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

● Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

● As with some penicillins and some other cephalosporins, transient hepatitis and cholestasis (jaundice) have been reported rarely.

● Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertension, dizziness, and somnolence have been reported.

● Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%; and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

● Slight elevations in hepatic enzymes

● Transient fluctuations in leukocyte count (especially in infants and children)

● Abnormal urinalysis; elevations in BUN or serum creatinine

● Positive direct Coombs' test

● False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinistix® tablets but not with Tes-Tape® (glucose enzymatic test strip, Lilly).

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CR-5014-B-849345

Drug-Induced Photosensitivity Reactions

by James M. Love, Pharm.D.

Many drugs, whether taken internally or applied topically, have the potential to induce photosensitivity reactions. These reactions are of particular concern in the summer months when sun exposure is more likely, and in our society where sunbathing (whether natural or under artificial sunlamps) is so common among most age groups. This article will discuss types of photosensitivity reactions, give examples of commonly used agents which have the potential to elicit photosensitivity reactions, and summarize the modalities currently being used to treat such reactions.

Photosensitivity reactions may be divided into two main types, phototoxic and photoallergic. Phototoxic reactions due to drugs are far more common than photoallergic reactions. A phototoxic reaction occurs when enough phototoxic drugs or drug metabolite is present in the affected tissue, and absorbs sufficient light radiation at the required wavelengths to elicit the damaging reaction. It is possible to elicit a phototoxic reaction in all patients receiving a phototoxic drug, provided that enough drug or metabolite is present in the tissue, and enough radiation reaches that affected tissue. Fortunately, this critical mix of drug and sunlight is seldom achieved and most patients do not experience frank phototoxic reactions. Phototoxic reactions are always confined to sun-exposed skin. Phototoxic reactions are less likely to occur in dark skinned or black persons, presumably due to the ability of dense melanin in the stratum corneum to filter out possible activating rays.

Phototoxic reactions may be further classified as being either acute or chronic reactions. Acute phototoxic reactions are characterized by an onset ranging from a few minutes to a few hours, with the reaction reaching a peak within hours to a few days after sun exposure. The reaction might manifest itself as an area of local erythema and edema, along with blister formation. Some reactions progress to hyperpigmentation and even desquamation resulting from cellular toxic agents formed when the drugs react with light radiation.

Chronic phototoxic reactions usually result from long term exposure to the sun while taking an agent with phototoxic properties. These reactions often present as wrinkling and atrophy of the skin, patchy

areas of hypo- and hyperpigmentation, yellow papules and plaques, keratotic growths, and may lead to skin cancer formation. The skin may also become increasingly fragile. Cutaneous blood vessels tend to rupture easily, leading to purpura.

Amiodarone is associated with a high incidence of acute phototoxic reactions. One study revealed a 55% incidence of phototoxicity, with 12% of those patients having severe cases. Reactions led to withdrawal of the agent in 8% of the cases.

The administration of psoralen derivatives along with exposure to long wave ultraviolet radiation (known as PUVA therapy) is a common treatment modality for psoriasis and some other skin diseases. Immediate phototoxic effects often seen with this therapy include erythema, burns, localized edema and blistering. Long term dermatologic side effects associated with PUVA therapy include freckles, acne, nail pigmentation, and hirsutism, among others.

Walnut-sized blisters (with or without preceding erythema) may appear on the skin following sun exposure in patients using nalidixic acid. These blisters usually occur on the extremities and rarely on the face. Eruptions may occur several days after discontinuation of nalidixic acid use, and may persist for up to four months.

Of the phenothiazines, chlorpromazine most often causes phototoxic reactions, described as erythematous and eczematous rashes. These reactions occur in around 3% of treated patients. Phototoxicity has also been reported with use of perphenazine, prochlorperazine, promazine, promethazine, thioridazine, and trifluoperazine.

This article courtesy of the Drug Information Service, University of Tennessee, Memorial Hospital Pharmacy. Comments on this article should be addressed to James K. Utt, Drug Information Coordinator, UT Memorial Hospital Pharmacy, 1924 Alcoa Highway, Knoxville, TN 37920 (615) 544-9125.

Tetracyclines are well known for causing phototoxic reactions. Erythema, edema, and blister formation occur frequently. Onycholysis (loosening of the nails) may also occur. It is important to note that demeclocycline is most likely and doxycycline and minocycline are least likely to induce phototoxic reactions.

Some nonsteroidal anti-inflammatory drugs (NSAID) are associated with occasional phototoxic reactions. The most prominent photosensitizing NSAID was benoxaprofen. However, that particular drug is no longer of concern since it has been withdrawn from the market due to liver toxicity. Among the currently marketed NSAID's, piroxicam is probably the most noteworthy for causing phototoxic reactions. Though rare (<1% of exposed patients), piroxicam photosensitivity can be serious. Usual symptoms of this reaction include an eczematous, erythematous, pruritic rash often accompanied by the eruption of vesicles or bullae.

Both quinidine and the thiazide diuretics have been associated with photosensitivity reactions, the appearance of which usually occurs after several months of therapy. Most often, the reactions appear as an exaggerated sunburn with erythema and edema; however, signs and symptoms resembling livedo reticularis or lichen planus may occur.

The antimicrobial sulfonamides have been reported to cause reactions of both the photoallergic and phototoxic varieties. Also, sulfonylurea derivatives used for treatment of diabetes mellitus have been associated with photosensitivity reactions. Topical coal tar preparations are well documented photosensitizers. Patients using coal tar products should be cautioned to completely remove them from the skin prior to receiving any significant sun exposure.

Photoallergic reactions are far less common than phototoxic reactions. This fact is better appreciated when one considers that true allergic reactions to most drugs are infrequent. A photoallergic reaction requires altered antigen-antibody or cell-mediated hypersensitivity specific for each individual. The clinical presentation of a photoallergic reaction may at first closely resemble that of a phototoxic reaction, differing later in the fact that photoallergic reactions may often spread to areas not having been exposed to sunlight. The hallmark sign of a photoallergic reaction is seen on histological examination of the affected tissue, and reveals the presence of a dense perivascular round cell infiltration in the dermis. By far, the majority of photoallergic reactions occur subsequent to prior contact exposure to the sensitizing agent. Photoallergic reactions to systemic agents are rare.

The accompanying table lists some commonly used photosensitizing drugs and a brief description of the clinical presentation of the more common reactions they elicit.

Common Drugs Which Can Cause Photosensitivity Reactions

| Drug | Manifestations |
|------------------------|--|
| Amiodarone | erythema, slate gray pigmentation |
| Coal tar derivatives | erythema, melanosis, prickling sensation |
| Methoxsalen/trioxsalen | erythema, edema, bullae |
| Nalidixic acid | erythema, rash, bullae, skin fragility |
| Phenothiazines | erythema, eczematous reaction, slate gray pigmentation |
| Piroxicam | bullae, eczematous reaction, erythema |
| Quinidine | erythema, eczematous/lichenoid eruption |
| Sulfonamides | erythema, eczematous reaction |
| Sulfonylureas | erythema, eczematous reaction |
| Tetracyclines | bullae, erythema, skin fragility, onycholysis |
| Thiazide diuretics | erythema, eczematous/lichenoid eruption, bullae |

Treatment of photosensitivity reactions is not different from that of most other inflammatory skin reactions. A variety of agents may be used in treatment, including cool, wet dressings and soothing lotions. Topical corticosteroid preparations such as hydrocortisone and triamcinolone creams may be helpful to reduce the eruption of rashes and the itching often associated with the reactions. Also, systemic antipruritic agents such as hydroxyzine and cyproheptadine may be administered. Although it is not normally recommended, use of systemic corticosteroids such as prednisone and methylprednisolone is sometimes needed to control the symptoms of phototoxic reactions. None of the above treatment modalities is curative, however, and if possible, the causative agent should be discontinued. At times, discontinuation of the offending drug is therapeutically impossible, however. In such situations, liberal use of sunscreens and strict minimization of sun exposure is warranted. (References available on request)

calendar



December 1—MSHP Monthly Meeting
 January 18–25—MPhA Trip to Aruba
 February 5—MPhA Mid Year Meeting
 March 12—BMPA Annual Banquet/Dance

Continuing Education

Continuing Education Quiz

The Maryland Pharmacist DECEMBER, 1988

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by March 1, 1989. A continuing education certificate for one contact hour (one credit) will be mailed to you within 30 days. Please type or print clearly.

Name _____

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Is this program used to meet your mandatory CE? Yes No

Did this article achieve its stated objectives? Yes No

How long did it take you to complete the program? _____ minutes

OTC Antiemetic Remedies

1. The proposed mechanism of action by which OTC antiemetics alleviate motion sickness includes all of the following EXCEPT:
 - a. inhibiting the reception of impulses by the CTZ.
 - b. raising the level of the vomiting threshold in the cerebral cortex.
 - c. depressing impulse conduction through the vestibular apparatus.
 - d. reducing the excitability of receptors in the labyrinth.
2. All of the following have been approved for OTC sale for treatment and prevention of motion sickness EXCEPT:
 - a. cyclizine.
 - b. dimenhydrinate.
 - c. chlorpheniramine.
 - d. meclizine.
3. The labeling of OTC antiemetics must contain a warning against self-medication by persons with which of the following diseases?
 - a. Asthma or glaucoma
 - b. Diabetes or thyroid disease
 - c. Heart disease or high blood pressure
 - d. Kidney disease or liver disease
4. The body's chemoreceptor trigger zone is located in the:
 - a. brain stem.
 - b. cerebral cortex.
 - c. inner ear.
 - d. medulla oblongata.
5. The antiemetic that is safe and effective as an OTC antihistamine, antitussive and sleep aid is:
 - a. Benadryl.
 - b. Dramamine.
 - c. Bonine.
 - d. Marezine.
6. The most effective preventative agent against motion sickness is reported to be:
 - a. meclizine.
 - b. diphenhydramine.
 - c. metoclopramide.
 - d. scopolamine.
7. The proposed mechanism of action for phenothiazine antiemetics is to:
 - a. inhibit dopamine receptors.
 - b. stimulate adrenergic receptors.
 - c. inhibit serotonin receptors.
 - d. stimulate cholinergic receptors.
8. The OTC antiemetic that is approved for use in children as young as two years of age is:
 - a. chlorpheniramine.
 - b. dimenhydrinate.
 - c. cyclizine.
 - d. diphenhydramine.
9. The body's equilibrium center is located in the:
 - a. reticular formation.
 - b. cerebral cortex.
 - c. inner ear.
 - d. medulla oblongata.
10. The major reason Antivert is available only on prescription while Bonine can be sold OTC is because Antivert:
 - a. is available in a sustained release dosage form.
 - b. contains additional ingredients.
 - c. is manufactured in additional strengths.
 - d. has additional indications.

Classified

THE YOUNG PHARMACISTS CAUCUS is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Duff's Smorgasbord on Westview Mall Road, Beltway Exit 15-A. Visitors are welcome. For further information, contact President Stephen J. Provenza at 433-9049.

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PHARMACISTS WANTED. For part time work at Hancock Pharmacy, Hancock, Maryland. Contact Jay at (301) 678-5534 or 582-2200.

APHA SEEKS EDITOR. APhA seeks a highly qualified, dynamic individual to be Editor of *American Pharmacy* and to head the association's Editorial Department. We seek an experienced pharmacist/editor with a strong editorial vision for pharmacy, editorial, and political judgement. Responsibilities include broad editorial direction for periodicals, editorial development of books, managing staff and budget. Please submit resumes to Laura C. Lawson, Director of Publications Management, at APPhA.

MPhA Mid-Year
February 5, 1989
Annapolis Ramada

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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FDA HOTLINE FOR AIDS information is 800-432-AIDS.

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PHARMACIST WANTED. Full time pharmacist for independent store in the Shenandoah Valley. Paid insurance coverage. No Sunday hours. Please call collect (703) 635-3115 or write W. E. Herr, Jr., President, P.O. Box 1277, Front Royal, VA 22630-1277.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your type-written ad to 650 West Lombard St., Baltimore, Maryland 21201.

PHARMACY RX ITEMS, broken containers, fast and medium movers for sale at reduced prices. Contact Preston Pharmacy at (301) 673-2318. Pharmacist closing store.



Next Month—
Pneumonia: A Still
Deadly Enemy



Their diverse ideas help keep us in touch with the pharmacy profession.

Every summer, they bring us the benefit of their years of experience. They're our Pharmacy Consultant Panel.

They come from all over the country, from a variety of disciplines. They come to talk, to listen, and to share their enthusiasm for a profession that's seeing its responsibilities grow to meet its capabilities.

The 1988 Pharmacy Consultant Panel:

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Assistant Director of Pharmacy
for Clinical Services & Research
Erie County Medical Center
Buffalo, New York

John J. Fegan
Vice President, Pharmacy
Operations
Pay 'N Save, Inc.
Seattle, Washington

Darwyn J. Williams
President, Williams Drug, Inc.
Webster City, Iowa

Thomas R. Temple
Executive Vice President
Iowa Pharmacists Association
Des Moines, Iowa

M. Patricia Lee
Director of Pharmacy
UCSD Medical Center
San Diego, California

Back row, left to right:

C. Fred Toney
Sales & Merchandise
Senior Vice President
McKesson Drug Company
San Francisco, California

Herman L. Lazarus
Director of Pharmacy
University of Alabama
Hospitals & Clinics
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John K. Middleton
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Thomas M. Ryan
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Consumer Value Stores
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Jack R. Cole
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University of Arizona
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